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The Process of Medical Device Development
- how it presents a challenge to traditional product development methodologies

by Peter J. Turner

THE PROCESS OF MEDICAL DEVICE DEVELOPMENT
- HOW IT PRESENTS A CHALLENGE TO TRADITIONAL PRODUCT DEVELOPMENT
METHODOLOGIES

by

Peter J Turner

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Approved by Assoc Prof Ian S Maddox,
Academic Director (Auckland)
Programme Director (Engineering & Technology)
College of Sciences

Supervisory Committee: Dr Kevin Low
Prof. Allan Anderson

Institute of Technology & Engineering,
Palmerston North

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This thesis was born out of a sense of frustration with the process of Medical Device Development in New Zealand; I hope that this study will make a difference.

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AIM

The New Zealand Government is encouraging manufacturers to develop markets for high value, knowledge based products. Medical Devices [MD] fit well within this policy since they are generally produced in limited volumes for niche markets. The complexity of many devices and restricted marketing opportunities discourages countries with developing economies from copying them.

The local market is too limited however to justify the expenditure required for the R&D of sophisticated technology and the manufacturer must ultimately seek international markets. Before a medical device can be accepted in any developed country however, it must comply with international standards.

Standards are evolving to support global commerce, easing the burden on manufacturers to comply and helping to ensure that users receive safe medical devices 124

Business structures utilised for Medical Device [MD] development must utilise multidisciplinary teams with a consumer focus to achieve success.

Compliance issues must be factored into the design of every device from inception. For the small to medium manufacturer to be aware of and understand all of the issues involved in every international market, is a daunting task.

A possible solution is to employ a consultant with the requisite knowledge, however the cost of advice during the period of development is a burden when the cash outflow is maximum! The industry in NZ is also immature and few individuals, including the Ministry of Health MedSafe staff, have sufficient knowledge to prevent costly delays and possible reworks for unforeseen design faults.

Marketing complex MD's internationally within this regulated environment requires resources and knowledge beyond the resources of the micro- and small medium- enterprises that are the lifeblood of the New Zealand economy.

The aim of this thesis is to develop a systematic management model to guide the medical device manufacturer along the path towards compliance in major international markets.

ABSTRACT:

Medical Devices [MD] represent special challenges to the designer and manufacturer. They range from disposable, single use articles to extremely complex and expensive technologies. While single use devices may be simple in concept and easily manufactured, they nevertheless may be invasive or could threaten human life if inappropriately used. For consumables packaging to maintain sterility from factory output to the operating tray is an important requirement. Such devices, in common with far more sophisticated equipment, may be assigned a classification requiring tightly controlled manufacturing and inspection systems that may vary between different jurisdictions.

Quality management systems increase overheads to the already considerable investment incurred during R & D. Audit trails required by these systems become tortuous and difficult to validate as components are sourced increasingly from low cost base countries.

The increasing use of microprocessor controlled wireless network technology increases radio frequency clutter and electromagnetic interference between medical devices can result in injury or death.

Most countries now insist on guarantees that toxic substances cannot be released by a product into the environment during its lifecycle or when disposed of.

International protection of intellectual property presents challenges for New Zealand manufacturers with limited resources. Frequently the designer/manufacturer needs an in depth understanding of the clinical context for the equipment including a knowledge of human physiology and anatomy for the application. Current literature about allied technology must be reviewed and a business plan developed that exploits the opportunity presented by the proposed advances in the development of a new MD applying current theoretical knowledge.

Many developments supercede historical technology, introducing challenges for the practitioner/operator to understand its operation and optimise its performance. Factoring patient & practitioner education into the distribution of MD's significantly increases the cost of marketing.

To gain access into international markets MD's must comply with stringent standards for safety and performance.

A case study examines these issues in relation to the development by the author of MD's to enhance vision and conduct tests of visual performance, the Librus 300 & 600.

This study illustrates many of the difficulties the New Zealand Manufacturer faces and suggests management structures, processes and development systems that would facilitate the process and an infrastructure to support it.

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1. New Zealand in the Context of International Medical Device Development

1.1 Introduction

Medical Devices [MD] are a special class of Consumer Products; they have a *medical purpose* and include those used for the *in vitro* examination of specimens derived from the human body.

A Global Harmonization Task Force (GHTF) is encouraging global convergence in the definition of a MD as regulatory systems evolve. This should facilitate trade whilst preserving the right of participating members in different jurisdictions to address the protection of public health by regulatory means considered to be most suitable. ¹ Quote:

'5.0 Harmonized definition of the term "medical device"

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;*
- investigation, replacement, modification, or support of the anatomy or of a physiological process;*
- supporting or sustaining life;*
- control of conception;*
- disinfection of medical devices; and*
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;*

and

b) that does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.'

Over-riding this definition are a number of notes:

'Note 1: The definition of a device for in vitro examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials, and related instruments or apparatus. The information provided by such an in vitro diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some in vitro diagnostic devices, including reagents and the like, may be covered by separate regulations.'

Note 2: Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are

- *aids for disabled/handicapped people; [also known as Assistive Devices – see Chpt 1.16-Box]*
- *devices for the treatment/diagnosis of diseases and injuries in animals;*
- *accessories for medical devices; [see Note 3 below]*
- *disinfection substances; and*
- *devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.*

Note 3: Accessories intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose should be subject to the same GHTF procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification than the 'parent' device.

Note 4: Components to medical devices are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device. In some jurisdictions, components are included in the definition of a 'medical device'.

1.2 Classification Rules for Medical Devices

As with the definition of MD's, the Global Harmonization Task Force (GHTF) are actively promoting a harmonized Medical Device Classification – ^{2,3} See Figure 1.

| CLASS | RISK LEVEL | DEVICE EXAMPLES |
|-------|--------------------|--|
| A | Low Risk | Surgical retractors / tongue depressors |
| B | Low-moderate Risk | Hypodermic Needles / suction equipment |
| C | Moderate-high Risk | Lung ventilator / bone fixation plate |
| D | High Risk | Heart valves / implantable defibrillator |

Figure 1. Proposed general classification system for medical devices

Simple, non-invasive devices require less regulation and need to meet less onerous standards than more complex, potentially invasive devices. See Figure 2. ³

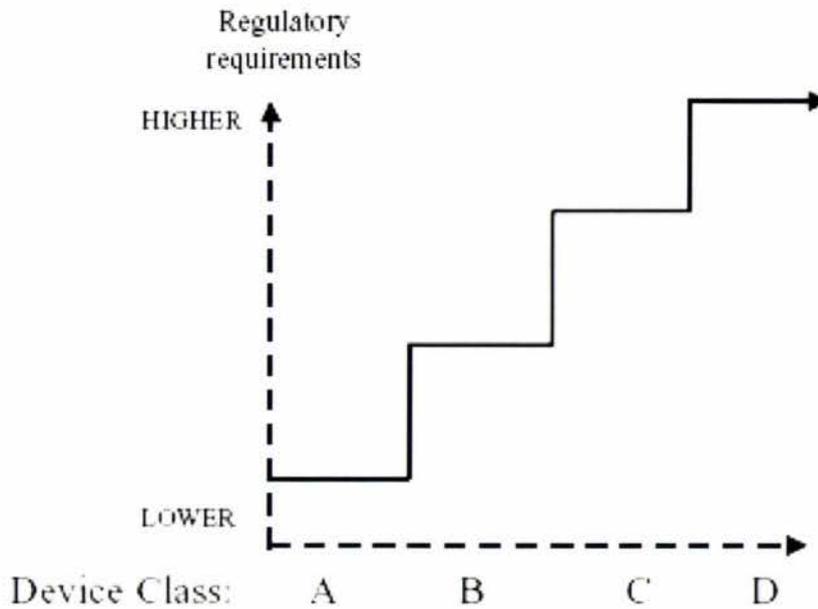


Figure 2: Conceptual illustration of regulatory controls ^{2,3}

These regulatory controls will be discussed in Chpt 4 and may include

- operation of a quality system (recommended for all devices);
- technical data;
- product testing using in-house or independent resources;
- documentation of clinical evidence to support the manufacturer's claims;
- the need for and frequency of independent external audit of the manufacturer's quality system; and
- independent external review of the manufacturer's technical data.

1.3 Demographics

Healthcare systems in every country are facing tremendous challenges; for the developing countries it may be from nutritional or water borne diseases, the impact of the failure of public health policies resulting in the spread of HIV/AIDS or the collapse of social structures from armed conflict.

As life expectancy rises in developed countries, the population of elderly people are requiring longer medical care and the number of elderly committed to hospitals or nursing homes because of geriatric disorders or chronic diseases is growing. ³

Population ageing is not unique to New Zealand or even to 'developed' nations. The transition to lower mortality rates and lower fertility rates has occurred, or is occurring in other countries, often at a much faster rate than in New Zealand. Population ageing is therefore a worldwide phenomenon. See Figure 3 below. ⁴

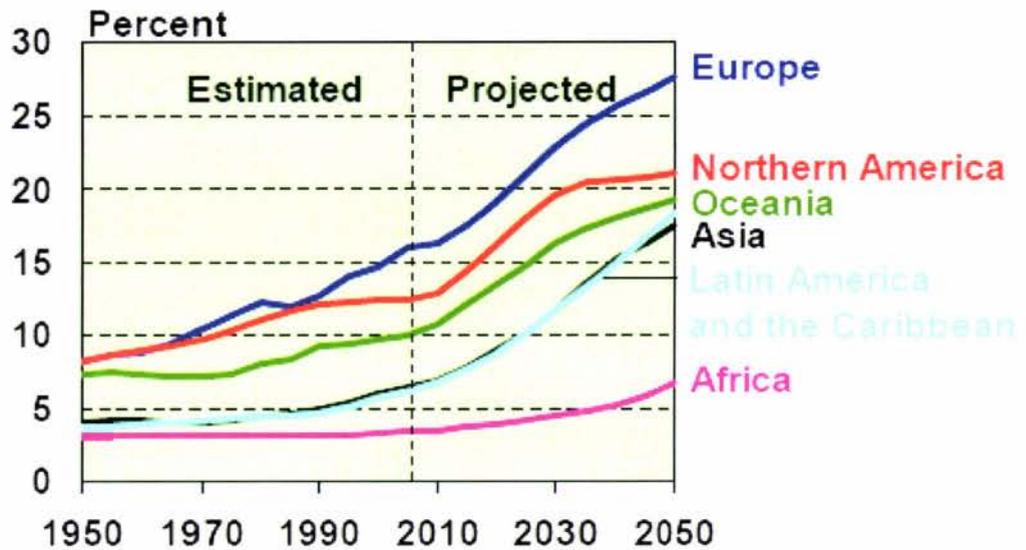


Figure 3 Proportion of Population Aged 65+ by Global Region

The population's expectations for health services can realistically never be met and the budget must be 'managed' by

- prioritising expenditure for services and capital investment;
- deferring purchases by passive or active bureaucratic inertia;
- government tendering for generic products;
- reducing choice to achieve economies of scale;
- shifting the threshold criteria for public services such as surgery;
- moving patients out of hospital beds post-operatively as quickly as possible;
- performing surgery and pre- and post- operative care as far as possible on an;
- outpatient basis, outpatient basis;
- decentralising primary and secondary care – transferring care from hospital outpatient clinics back to General Medical Practitioners or allied health professionals, and

- relying more on self-monitoring systems and home-monitoring equipment.

Self-monitoring systems and home-monitoring equipment should provide new markets for innovative and cost effective MD's in New Zealand.

1.4 Commercial Value of MD's

Manufacturers of diagnostic/treatment – low to med volume production/high value MD's support their products with disposables [alt. consumables] - high volume-low value products. Disposables may be used in association with diagnostic tests [syringes, swabs] or as adjunct devices to diagnostic/treatment medical technology [blood sugar test strips].

MD's may therefore be divided into medical diagnostics and medical capital goods segments. Because of the diversity of consumers it is difficult to quantify the demand for each category, however for the year 2004, Germany quotes figures of an export ratio of over 54% in the medical consumables, and of 62% in the medical capital goods segment. ⁴

Analysts estimate the world market for medical devices at US\$250 billion for the year 2005. After the United States and Japan, Germany is the third-largest market for medical devices. ⁴ See Figure 4 below:

| | EU15, United States, Japan 2002 | EU15, United States, Japan 2010* | Germany 2002 | Germany 2010* |
|--|------------------------------------|-------------------------------------|-----------------|------------------|
| Hospitals | 90.6 | 126.3 | 6 | 8.6 |
| Assisted care facilities | 9.3 | 12.7 | 1.2 | 1.7 |
| Doctors' offices | 26.1 | 41.4 | 2 | 3.1 |
| Dentists' offices, dentists' laboratories | 27.7 | 35.8 | 3.9 | 5.2 |
| Health care retail, hearing aids, opticians | 6.6 | 8.6 | 0.5 | 0.7 |
| Pharmacies | 6.6 | 8.6 | 0.5 | 0.7 |
| Rescue, physiotherapy, alternative practitioners | 6.4 | 9 | 0.6 | 0.8 |

* estimated

Figure 4 Demand for Medical Technology in the Health Sector 2002 – 2010 (EUR billion)

1.5 Scoping Opportunities for Ophthalmic Medical Devices

The following discussion/processes could be adapted for any medical field, however as the author is most familiar with the field of visual optics, it has been scoped for potential markets.

1.5.1 Customer Problem/Need

Different levels of eye care are used to correct deteriorating vision, detect, monitor and treat eye disease.

1.5.1.1 Assessment of Visual Performance

Visual performance is assessed to

- provide quality vision correction through the use of prescription glasses, contact lenses;
- assess visual fitness for public services, e.g. the military and police;
- determine if the patient is fit for a vocation (such as within the heavy transport) or to perform a specific function (such as colour matching); and
- advise on visual ergonomics, eye protection & visual health.

1.5.1.2 Diagnosis & Treatment of Disease

Routine visual examination frequently detects asymptomatic eye disease resulting in early diagnosis of diseases (such as glaucoma and diseases of the retina). This generally results in more effective treatment and a better patient outcome. Continuing eye care may be necessary however to

- treat eye disease;
- analyse the physical properties of eyes for surgery; and
- monitor the eye to evaluate treatment outcomes.

1.5.1.3 Surgery

Eye surgery may

- correct visual errors by corneal refractive surgery or the implantation of lenses;
- reduce pressure within the eye by performing 'bypass' operations or the installing tubes, shunts, etc; and
- treat or correct a variety of internal and external eye conditions resulting from disease, congenital abnormalities or trauma.

1.5.2 Value

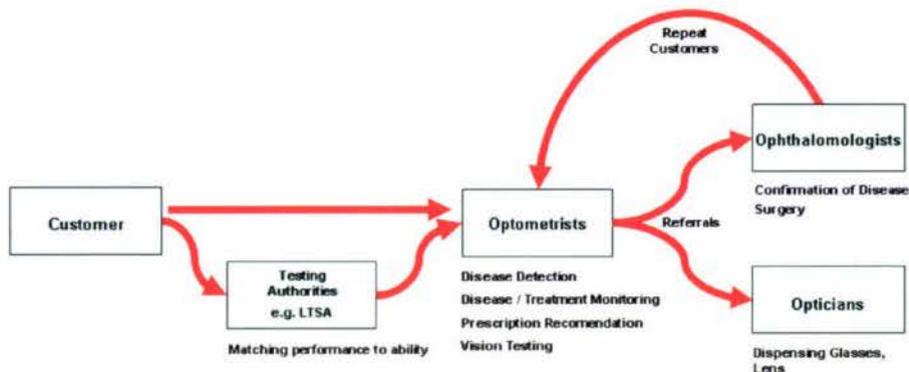


Figure 5. The Value Chain

High value equipment is used for the detection and treatment of disease, while lower value equipment is used for visual examinations.

1.5.3 Market Attractiveness

The global market is \$US 650 million annually, expected to reach \$US770 million by 2008 ⁶ The purchasers are known early adopters with both the financial capability and competitive drive to acquire novel technologies. The industry has a history of novel disruptive technologies displacing older, poorer performing technologies.

1.5.3.1 Assessment of Visual Performance

Ophthalmic services are expected to grow as the population ages causing an increase in demand for eye examinations and corrective therapies associated with cataract, diabetes, and age related maculopathy.

The measurement of vision is for determination of capability, for driving cars, piloting aircraft, etc. Vision testing for external agencies such as land transport agencies is mature and unlikely to change without new legislation.

1.5.3.2 Diagnosis & Treatment of Disease

The diagnosis and treatment of eye disease is a large, high value and growing market. Eye diseases are becoming more prevalent as the population ages and are increasing in the older, more affluent members of

the community as a complication of hypertension and obesity. Diseases of the retina are also increasing, especially those associated with diabetes. Cataract operations are increasing with the aging population and frequently require follow-up care. The same devices used to diagnose disease are used in the follow-up care of patients that have had eye surgery. Glaucoma is estimated to affect 1% to 2% of the western population.

The target markets for MD's are optometrists and ophthalmologists. Any need for new devices must be led by these target markets. Both professions purchase MD's that measure visual performance and utilise them in their practice.

Optometrists specialise in vision problems. Optometrists are visual scientists who do not perform surgery, but may therapeutically treat eye diseases. They use specialised equipment to perform a full examination of all structures of the eye to:

- determine spectacle prescriptions that may be dispensed to the patient or provided as a script to be dispensed by an optician
- make recommendations to external testing authorities as to the visual performance that might reasonably be expected of an individual
- monitor and diagnose eye disease before referring patients to ophthalmologists or other health professionals
- provide pre- and post-operative surgical and shared medical care for patients

Optometrists provide more than two thirds of eye care in most western countries (excluding some European countries). The number of optometrists in the world is expected to grow as countries develop their healthcare services and populations continue to age. Optometrists work mainly as solo practitioners or in small group practices.

Ophthalmologists are specialist eye surgeons and physicians. They perform eye surgery and treat eye disease. They are often associated with larger health providers, such as public or private hospitals and more recently have pooled their resources in large group practices with very comprehensive facilities to provide full primary and secondary day care. These facilities are very significant purchasers of modern MD's to provide a standard of care unattainable in public facilities.

1.5.3.3 Surgery

The number of treatments is increasing, due to an aging population and technological advances. U.S. patients underwent more than 5.4 million cataract, refractive, retinal and glaucoma procedures in 2004 and this is expected to increase to nearly 7 million by 2008.⁶ In New Zealand, the government has pledged to double the number of cataract operations over the next three years, to 15000 operations annually at a cost of NZ\$34 million. Medical devices to measure visual performance, diagnose and treat eye disease have high margins.

1.6 Drivers & Trends

In the long term, the greatest trend in the market is the growing availability of high value treatments carried out by ophthalmologists. Associated with these treatments is equipment that provides the surgeon with surgical information and monitors the outcome of the treatment. See Figure 6 below.

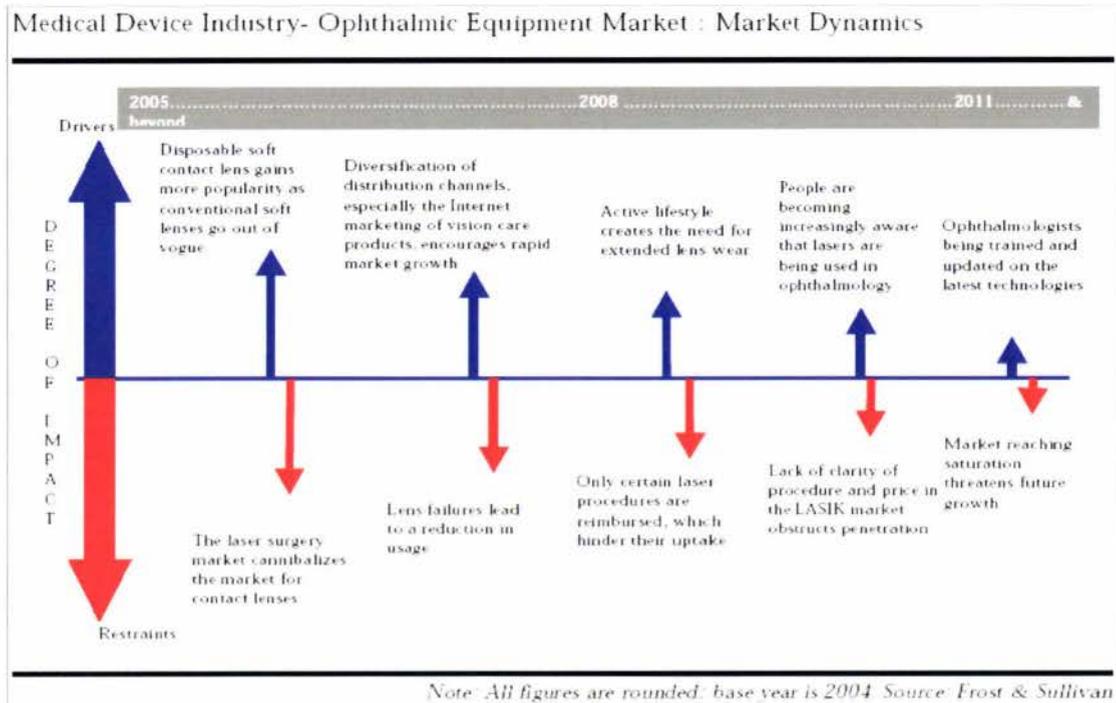


Figure 6. Drivers & Trends ⁶

1.6.1 Assessment of Visual Performance

Demand is driven by demographics, fashion, improvements in contact lens technology and changing healthcare practices. Most important is the aging population, which is increasing demand for eye examinations and eyewear. However tests for elderly drivers have become less restrictive in recent years. This is for political expediency and is contrary to commonsense, for it is an indisputable fact that the visual performance of the aging eye has severe limitations. Fortunately many elderly drivers, even if they cannot reach the legal standards, drive well within their limitations – for example, only during daylight hours and not into the sun!

1.6.2 Diagnosis & Treatment of Disease

As the population ages, there is a strong trend towards increasing number of diagnostic tests, especially for cataracts, glaucoma and diseases of the retina. Incidences of diabetic retinopathy are increasing, with a disproportionate increase in Maori and Polynesian peoples.

There is a demand for monitoring the outcomes of treatment (whether surgical or pharmacological) with advanced instrumentation.

There is an increasing need to store results from any vision examination device, preferably digitally and immediately (through direct links to patient management systems), to provide temporal information. 3D digital images are preferred to provide more graphic examples to explain to the patient the nature of their condition and to provide diagnostic cues for the practitioner. A nascent industry surrounding the merging of images from different modalities is developing to provide richer information for ophthalmic practitioners and valuable records for patient management.

1.6.3 Surgery

Corneal refractive surgery and advances in treatment for example in retinal surgery is driving average costs for ophthalmic devices upwards. These devices expand the eligible patient population for ophthalmic procedures.

1.7 Medical Devices and Diagnostics in New Zealand

New Zealand has particular strengths in the fields of agriculture, animal health, forestry, human nutraceuticals and pharmaceutical medical research. These capabilities reflect New Zealand's historical focus on the primary industries as well as the strengths it is building in relatively new areas, such as human health.⁷ The analysis of medical device companies and their inclusion in the biotechnology sector highlights the decisions about what falls within the biotechnology sector. While regulatory authorities clearly distinguish between devices and cell-based or pharmaceutical innovation, these activities are united by their focus on their goal to develop and commercialise technology and research in healthcare.⁷

The majority of medical device companies in New Zealand fall into the classification of importers or distributors, rather than developers and manufacturers. Medical device manufacturers can be further segmented in terms of the category of devices that they produce. These companies have most in common with biotechnology companies in terms of the regulatory complexity, level of innovation and investment required for commercial success.⁷

The sector is dominated by Fisher and Paykel Healthcare which has spun off people and talent into the pool of many of the smaller device companies.^A

A Fisher & Paykel Healthcare Corporation Limited 2006 Sales: NZ\$289,550,000 Employees: 1276
Business Description: The Group's principal activities are designing, manufacturing and marketing heated humidification products and systems for use in respiratory care and the treatment of obstructive sleep apnea. In addition, it also manufactures and markets patient warming and neonatal care products, and infant resuscitators and CPAP systems designed to improve infant respiratory function.

Of the approximately 60 companies who are developers and manufacturers of medical devices, only 15 - 20 focus on devices which are Class IIa or higher. The Key Participants in the NZ MD manufacturing sector is shown in Figure 7.⁷

| Key participants | |
|------------------------------|--|
| Private Sector | Public Sector |
| λ Fisher & Paykel Healthcare | λ Liggins Institute |
| λ BrainZ Instruments | λ University of Auckland / Uniservices |
| λ Sunshine Heart | λ Auckland University of Technology |
| λ Pacific Edge Biotechnology | |
| λ Acept Medical | |
| λ Enztec | |
| λ KODE Biotech | |
| λ Arotec Diagnostics | |

Figure 7. Key Participants

Of the private sector participants below, five are still listed as NZ companies and the remainder are Australian or international subsidiaries. Diagnostic reagents, pharmaceuticals and delivery devices feature in the product range of the remainder. Of the Major Achievements/Milestones during 2004 & 2005, only two organisations were producing manufactured products. See Figure 8.

| Major achievements / milestones during 2004 and 2005 | |
|--|--|
| Organisation | Achievement |
| Fisher & Paykel Healthcare | Releases series of new face mask for use in the treatment of obstructive sleep apnea in March 2004, October 2004 and September 2005 Releases new humidifier system for use in Intensive care environments in April 2005 |
| Sunshine Heart | Completes secondary offering for A\$3.3m in December 2005 |
| BrainZ | Signed a 2 year distribution agreement with GE Healthcare in October 2004 Completes IPO raising A\$13m on ASX in December 2005 |
| Enztec | Received FDA approval to sell a new device to assist hysterectomies |
| Pacific Edge Biotechnology | Secured \$1.04m grant from Technology New Zealand in 2005 to continue development of a gastric cancer diagnostic tool |
| KODE Biotech | Licenses blood-typing technology to CSL (Australia) in 2004 and NASDAQ-listed Immuncor in July 2005 |

Figure 8. Major Achievements in 2004/5⁷

New products released by NZ manufacturers continue to be predominantly biological or biochemical and it is significant that only one MD is represented in Figure 9.

Recent Examples of New Product Launches

| Company | Product | Type | Description | Date and Stage of Advancement* |
|-----------------------------------|-----------------------------|------------------------|--|---|
| AgResearch | Clover Root Weevil | Agbio | Discovery and testing of a bio-control (wasp) for the clover root weevil | First released in January 2006 |
| BioVittoria | PureLo | Nutraceutical | PureLo is a non-caloric food additive that is 300x sweeter than sugar. It is made from the concentrate of the Luo Han fruit, which is grown exclusively in China. | In May 2006 PureLo was declared GRAS (generally recognised as safe) by an independent panel under FDA guidelines. This opens the lucrative US market ahead of PureLo's imminent launch through the distributor Barrington Nutritionals |
| Blis Technologies | K12 Fresh Breath Range | Health | Mouth products to combat halitosis utilising their patented K12 bacteria. Includes Mouthwashes, chewing gum and other products | With the first commercial shipment arriving in North America in November 2004, Blis has released a number of products over the last two years |
| Brainz Instruments | RecogniZe Software | Medical Device Support | RecogniZe software is an upgrade to BrainZ's popular BRM2 baby brain monitor. This new software will help medical practitioners to detect when neo-natal babies have seizures | Commenced sales in New Zealand and Australia on the 1st of September, 2006. Has applied to FDA for certification for USA sales. |
| Catapult | LoinMAX3 and MyoMAX3 | Agbio | DNA marker tests to identify sheep with genes that have a greater chance of producing desired characteristics | Launched in Spring/Summer 2005 |
| GraceLinc Ltd (Crop & Food) | Glucage | Nutraceutical | Glucage is a purified form of barley, which has all the health benefits of high levels of soluble fibre, while giving food a creamy texture | Commencing small scale commercialisation in 2004, GraceLinc is now in collaboration with an American and a European partner to aggressively market overseas. While currently selling into Japan and the US, there is strong interest in Germany, Italy, Thailand and Taiwan |
| Keratec | Functionalised Keratin | Health Products | Keratec's novel methods to solubilise keratin, and yet retain its functional properties, is being incorporated into a number of products. These include Cynergy (cosmeceutical), Keratec (topical ingredients), Cynatine (health supplement) and Proine (animal health and care supplements) | The topical Keratec range has a number of products for the care of hair, skin and nail, with more under development. The Cynergy range of cosmeceuticals was released for sale in March, 2006. Cynatine FLX was released for sale in July 2006 |
| Landcare Research | Equip-F | Agbio | Developed by Landcare and commercialised by Sreat Instrument the Equip-F device automates the process of soil testing | Sales of the device to laboratories in China and Scotland commenced in early 2006 |
| Livestock Improvement Corporation | DNA Punch | Agbio | A new DNA sampling technique for quicker and more convenient sampling | Launched in March 2006 |
| ZyGEM | DNA extraction bio-reagents | Diagnostics | Bio reagents designed to increase the speed and accuracy of the DNA extraction process, across a diverse range of applications across the human, plant and animal DNA testing industries | First commercial user announced in February 2006 |

Notes: *As at September, 2006
 Source: Public Domain

Figure 9 Recent Examples of new Product Launches ⁷

1.8 Technological Synergies to Promote MD Development

MD's have traditionally been serially developed by well established manufacturers; Topcon, Carl Zeiss, Heine, etc. They build on their established manufacturing capability; indexing improvements and adding features or accessories to their existing stable of products. With a sophisticated in-house R, D & design capability they are able to respond relatively quickly to technological trends & customer suggestions.

Particularly in the US, many new innovations are conceived by Clinicians or Technologists who have recognised an unmet clinical challenge. Frequently they identify a significant improvement in the performance of a medical or surgical process, procedure or instrument that could be achieved by the adoption of a new technology. If sufficiently motivated, they may initiate the IP process and take the development to the prototype stage.⁸ The success or otherwise of the development depends principally on adequate funding, but it is essential that a design team with the appropriate mix of skills is consistently involved.

MD's are becoming increasingly sophisticated as they incorporate embedded software for enhanced functionality and higher level software for data analysis and patient management. A trend toward combination products involves crossover technologies in materials science, electronics, biochemistry and pharmacology.^B

According to UC Irvine, 50% of all MD firms are located in Southern California and to support the rapidly growing industry base, they are now offering new business courses.⁹

To provide the synergies for successful integration of complex developments not only requires an appropriate range of technologies to be accessible, but also sophisticated quality management. The project manager must have a very good understanding of the language of the technologies to facilitate their integration. In effect they must 'broker' the process; bridging the disciplines, but most importantly focusing the team members on the prime objectives of the development to prevent inappropriate diversions. These brokering skills have evolved into the academic discipline termed Mechatronics defined variously, but selecting that of the Drebber Institute for Mechatronics, University of Twente:

***Mechatronics** is a synergistic approach to the integrated and optimal design of a mechanical system and its embedded control system, where solutions are sought that cross the borders of the different domains.*¹⁰

As well as being skilled enough to 'broker' solutions, individuals must create synergy between specialists, to ultimately promote a satisfactory outcome. However the language of super-specialties necessary to develop

^B A combination product is described as a product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.

leading-edge technologies is evolving so rapidly that a single individual is unlikely to appreciate all of the subtleties. There is always the risk that a contributor of a solution may fail to recognise that it is sub optimum for a particular application and the Mechatronics qualified manager has not understood the implications.

John Millbank of the University of Salford, U.K. summarized the system level approach:

*By definition, then, **Mechatronics** is not a subject, science or technology per se – it is to be regarded as a philosophy – a fundamental way of looking at doing things and by it's very nature requires a unified approach to it's delivery.* ¹¹

Such synergy is possible, only in exceptional circumstances in NZ because of the paucity of high tech firms, or if they exist - their inconvenient geographic distribution. Specialty manufacturers may be dispersed throughout the country and while communication is simplified using the internet for transfer of files and information, personal visits are often necessary to encourage co-operation and develop relationships. Discouraging synergy is the protective culture of the tertiary and government research institutions, alluded to below.

In NZ we do not enjoy the synergies possible with clusters of industries such as those in Southern California referred to above, and the problem of limited manufacturing capacity must also be factored into the process. NZ is consistently referred to as a country of Small Medium Enterprises [SME] but it is unlikely that the majority of policy makers have any understanding of the international definitions of the SME sub-groupings.

1. Micro 0 – 9 employees. [a few countries define Micro as 0 – 4 employees]
2. Small 10 – 99 employees. [NZ – 19 or fewer]
3. Medium 100 – 499 employees. [as is NZ, Australia & the USA. However for the EU it is 50 – 249 employees] ^{12,13}

Even though the definition of a SME in NZ is 19 or fewer employees and SME's comprise 96% of all enterprises in NZ, in reality most specialist NZ manufacturers are, by international standards Micro enterprises. ¹³ The result is that they have little capacity to buffer any sudden upsurge in demand for a new product.

The author had the experience many years ago of a US distributor 'discovering' his product and placing orders to be sustained at ten times the current production. While supply at this level was possible by restructuring the manufacturing facility, the additional overheads would have been financially ruinous if the

new client had subsequently withdrawn the demand. The sales opportunity had to be declined; the disappointed potential client was confused and disgruntled!

Meeting increased demand locally is obviously desirable; however the current reality is that manufacturers are more likely to outsource the production of components to low wage base countries because of their lower pricing structure and rapid response.

1.9 Organisational Structures to Support MD Development

The synergies in technologies required for MD development in the future may involve sophisticated supporting design and management infrastructure as well as technology industry groupings.

1.9.1 Design and Management Infrastructure

At least two companies in the USA have evolved to meet the challenges of the accelerated ideation process and to promote the synergies discussed above. These are the Sarnoff Corporation and TIAX LLC.

Sarnoff morphed from RCA's main lab into a for-profit enterprise whose services run from contract research to collaborative R&D. TIAX evolved from Arthur D. Little's Innovation and Technology Group and was founded more than a century ago. Sarnoff has a registered process they style 'Inventiate' [Invent, Create, Differentiate] and has in excess of 300 technical experts to focus on a project

- needing to get to market fast;
- with a burning desire to expand market share, or to enter new markets; and
- with issues in products or design that are chronic, costly, or creating significant loss. ¹⁴

Both companies boast significant laboratory facilities to resolve product, process and manufacturing issues. The founder and president of TIAX, Kenan Sahin suggests that following the dot.com bust investment in innovation has become so risky that while the founder/technologist was an entrepreneurial hero, innovation is perhaps only 5 -10% of the success – 90 to 95% is the implementation. ¹⁴ He now advocates entrepreneurial heroes!

A modest version of these models may provide NZ with a way forward to a viable R&D MD industry. See Chpt 6.

1.9.2 Technology Industry Groupings

There have been a number of strategies and structures adopted throughout the world to encourage

entrepreneurial activity in technology including MD development. These include:

- Incubators; ^{C 14,15,16,17}
- Clusters; and ^{D 18}
- Research Parks. ¹⁹

These geographic and organisational entities provide a supportive environment for entrepreneurial or start-up organisations. Support might include

- convenient access to road and public transportation; and
- an advanced fiber optic-based telecommunications infrastructure.

A "technology park" ¹⁹ is one that

- is linked with educational or research institutions;
- provides infrastructure and support services for businesses, particularly real estate and office space;
- performs a technology transfer function;
- performs an economic development function
- a high bandwidth Internet point-of-presence (POP) on-site;
- access to a skilled and educated work force;
- access to the faculty and students of major universities, medical colleges associated with Medical Centre sited nearby;
- close to downtown and an International Airport;
- a campus-like setting with sidewalks and nature trails;
- restaurants, lodging, recreation, and shopping within minutes;

C. According to the definition of the European Commission, "a business incubator is a place where newly created firms are concentrated in a limited space. Its aim is to improve the chance of growth and rate of survival of these firms by providing them with a modular building with common facilities (telefax, computing facilities, etc.) as well as with managerial support and back-up services. The main emphasis is on local development and job creation. The technology orientation is often marginal." ¹⁹

The US National Business Incubation Association defines the business incubator as "an economic development tool designed to accelerate the growth and success of entrepreneurial companies through an array of business support resources and services. A business incubator's main goal is to produce successful firms that will leave the program financially viable and freestanding." ²⁰

D A very basic definition of clusters: "geographical concentrations of industries that gain performance advantages through co-location"

- attractive traditional neighborhoods and excellent schools nearby;
- a business incubator, a Technology Innovation Center may be home to numerous new technology-based businesses; and
- technology and business development assistance from a Park staff that understands emerging technologies.

1.10 International Centres of Medical Device Innovation

The form of international centres of MD innovation may radically differ from industry to industry and country by country.

Switzerland has successfully specialised in the chemical and pharmaceutical industries by a strategy of concentrating on specialties. With their high-grade specialised products Swiss companies have established a world-wide presence, and often a market leadership.²⁰ However manufacturing is largely outsourced, while head offices and R&D are retained in Switzerland.

India, China and Singapore are closing the gap to the global elite in competition with Europe, the U.S. and Switzerland. New knowledge is sourced where it is available, cost-effective and where the general framework is right. As a consequence Roche has become the first pharmaceutical company to open a research centre in Shanghai.²⁰

There has been a significant shift of R&D in recent years to the US, not only in the output of new active ingredients but also in the convergence of the health sector in the development of 'combination products'.

Combination products bring together the best of both worlds – combining the efficacy of advanced therapeutics or drugs with the precision dosing made possible by sophisticated medical devices and delivery technologies. They provide innovative new ways to extend the life cycles of existing products, while providing consumers with reduced toxicity, fewer side effects, higher efficiency and improved patient compliance.²⁰

The 'clustering effect' of therapeutics industries is likely to attract congruent MD industries to develop diagnostic and delivery systems.

There are further examples of innovative pressures. Israel has a well developed military electronics technology, strong governmental support for industrial R&D and an influx of scientific talent from the USSR. This provides the wherewithal for thriving high-technology industries.²¹

Sweden has a very supportive social welfare system that has encouraged local solutions in the development

of assistive devices.

Germany's mature optics industry, [facilitated by militarization and two WW's] is world renowned for the production of ophthalmic, scientific lenses and instruments. Carl Zeiss claims that two out of every three micro surgeons worldwide use the company's surgical microscopes. ²²

'Building on Ireland's recent 'Celtic Tiger' economic growth, the Irish Government, through the National Development Plan 2000-2006 (NDP), has committed the expenditure of €2.48bn for research, technological development and innovation, as part of its policy to ensure that Ireland will be one of the foremost knowledge-based economies in the world. ²³ With 13 of the top 25 MD and diagnostic companies with established R&D teams in Ireland, they are positioning themselves for large scale co-ordinated programmes, targeted in micro-electronics, sensors, ambient intelligence, nano-electronics, photonics and bio-medical diagnostics and therapeutics.

Australia faces most of the same issues as NZ. Australia's biotechnology enterprises are predominantly small in size; the only large businesses being subsidiaries of multinationals. With a small domestic market and highly specialised products, most have a global orientation and more than three quarters are exporters. ²⁴

They [read also NZ!] suffer from a number of problems which combine to stifle investment and reduce the potential for innovation and commercialisation including

- declining government support for basic research and skills training;
- a business culture which does not favour expenditure on R&D;
- low expenditure on R&D in Australia by multinational pharmaceutical companies;
- a lack of financial resources for high-risk early-stage product development;
- inadequate management of intellectual property, particularly by public institutions;
- inadequate understanding among scientists of commercial matters and among business professionals of scientific matters;
- inadequate access of scientists to skilled technology transfer services;
- a shortage of industry expertise, particularly in management of product development; and
- lack of industry development compared with strong biomedical research effort.

Looking to the future, the literature from virtually every developed country discussed numbers of start-ups or proposals for industries developing around nano-technology and micro-electronics. These technologies will undoubtedly revolutionise treatments and diagnosis. NZ can only watch from the sidelines in these fields, however at the lower levels of technology, we have much to offer.

1.11 Standards Initiatives

The development of comprehensive and [globally] harmonised standards encourages manufacturers to enter into MD development. An example is the evolving wireless protocols which must provide range, security, integrity and non interference.

Software protocols, particularly with respect to data management, transfer and archiving is an area where a great deal of development is necessary to enable MD's to 'talk' to each other and to integrate with patient management systems. ^E The seminal developments of cross-platform software by Right Hemisphere in NZ provides the potential for some unique developments in medical imaging. ²⁵

ISO/TC 172 sets standards for terminology, requirements, interfaces and test methods in the field of optics and photonics. This includes complete systems, devices, instruments, ophthalmic optics, optical and photonic components, auxiliary devices and accessories, as well as materials. Optics and photonics is used in the meaning of generation, handling and detection of optical radiation including signal processing. ²⁶

The range of products comprises highly sophisticated complete optical systems down to 'simple' semi-finished products or components. The market for optical products is a global one, with a total market size of approx. US\$75 billions. ²⁶

It is expected that the photon will be the basis for a technical revolution in this century like the electron was the one for the 20th century. Optics and photonics are "enabling technologies" which will influence not only information technology, telecommunications, lighting and energy, but also industrial production and automation as well as healthcare and life sciences.

1.12 Optics Industry Initiatives

At present optics-related companies number more than 5,000 in the USA and their net financial impact amounts to more than US\$50 billions annually. This is expected to grow dramatically in the near future; optics technologies are rapidly becoming an important focus for new businesses in the global economy.

^E Most MD's have dedicated software to protect the manufacturer's IP. The back-up files may be available in a form that allows access to the information for management and study.

The COSE report on *Harnessing Light* alerted the world to the impact of optics on almost every field of human endeavour, but particularly in the human sciences.²⁷

Hoping to develop new industry in NZ capitalizing on existing optics based industries, academic and research institutions, Positive Wellington Business [PWB] sponsored a visit by Robert Breault in June 2002.

Breault is the founder and CEO of the Breault Research Organisation [BRO]. He is an active supporter of the optics cluster in Tucson, Arizona where the civic authorities have embraced the optics theme, facilitating infrastructure and publicising the industry with civic light displays and sculptures. The Arizona Optics Industry Association notes that approx 160 of the 200 members of the association are sited in 'Optics Valley' [Tucson].²⁸

Positive Wellington Business [PWB] intended to encourage the development of an optics 'cluster' in Wellington, focused on a number of key industries, tertiary institutions and Government organisations already involved in optics research and manufacturing. Breault interviewed researchers, academics, industry, local body and national government personnel, etc. throughout the country and provided a report outlining his concept for an industry initiative.

It was established that there was insufficient overlap between existing industries to enable synergy. To meet the competition of an open international market, the depth of expertise in NZ was insufficient. Faculty qualified in optics were unavailable and although the Universities were enthusiastic to incorporate optics courses into their curriculum, they would need to attract an academic champion with the knowledge of the international optical industry. Students would have to be attracted to study the discipline, requiring a great deal of effort and publicity. Even then it would be some time before graduating students would be available and because they would also be greatly in demand for the rapidly developing industries in the US and even for Australia, it may be very difficult to retain them in NZ.

NZ also lacks the 'drivers' provided by the laser, photonics, communications, space and particularly the defense industry, to encourage the development of a sophisticated R & D and manufacturing base. The co-chair of the Wellington Optics Cluster, Mr Martyn Cook formerly of Vega Industries Ltd, Porirua, noted that the astronomy industry is also extremely important in the US, not only associated with the study of space, but actually to support the surveillance and satellite communication programmes.

The culture of academia in the USA was notably different from New Zealand – they were obviously wealthy! Apparently once they had established their tenure and reputation, their university office became a consulting centre, frequently supported by PhD students and post doctorate research fellows.

During his study tour of the 'Optics Valley' Cook observed that dispersion of technology was very apparent; very few firms knew what the destination of the components would be; even their conditions of use were secret.²⁹

Companies such as IRL and Vega Industries have been successful in developing and supplying very sophisticated devices on a limited production basis – and this has drawn the admiration of the purchasers. The experience of Vega in particular has been that if they move into an existing market, even if they are competing with an inferior product, they 'beg a fight'. They have discovered that to defend their right to bid for a government project may cost more than the value of the contract.

In the absence of significant drivers such as research centres seeking to transfer and develop technology, military expansion or a sophisticated manufacturing base, NZ R&D is hampered with respect to developing a highly innovative optical industry. However it is well within our capacity to develop novel MD's with excellent commercial potential by outsourcing critical components developed for an alternative purpose.

1.13 Learning from Medical Misadventure – Designing for Patient Safety

Medical misadventure/error can be defined as the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim. Among the problems that commonly occur during the course of providing health care are adverse drug events and improper transfusions, surgical injuries and wrong-site surgery, suicides, restraint-related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities. High error rates with serious consequences are most likely to occur in intensive care units, operating rooms, and emergency departments.³⁰

Medical misadventure cost ACC \$47 million including GST, in 2004. It is also acknowledged that medical misadventure continues to have a "very high" under-reporting rate with just 20 per cent of cases reported. Patient safety studies by Professor Peter Davis, of the Christchurch School of Medicine, found that more than one in eight public hospital patients would suffer a medical mishap.³¹

Although many errors can be described as 'system' failures, a significant number are caused by poor design of MD's and/or the failure to apply good practice in human factors. As the FDA points out:³²

'Medical devices can sometimes harm patients, family members, or healthcare providers. The potential harm arises from two sources

- *failure of the device;*
- *actions of the user; (or use-related errors)*

Hazards associated with device use are a serious problem. A combination of influences leads to use-related errors with medical devices.

- *Medical devices can be complex.*
- *Medical devices are often used under stressful conditions.*
- *Users may think differently than device designers do.*
- *Consumers now use devices that were originally designed for experienced medical personnel.*
- *Authorities blame repeated use errors on the user, rather than on poor product design or inadequate instructions for use; there needs to be recognition of the importance of human factors.*

The frequency and consequences of medical device use errors far exceed those arising from device failures, therefore product developers must consider device use and use-related hazards to ensure that their devices will be safe.'

1.14 ICT

Although many medical devices are not computing devices *per se*, a growing number of them are relying on Information and Communication Technology [ICT], whether by means of logging or telemetry functions, e.g. portable or home healthcare devices, or through their deployment in networked hospital wards.³²

The Rotorua General Practitioners Group [RGPG] have developed a universal wireless network that blankets the Rotorua area. This allows access to a centralised database for practitioners from any venue, including their car, a residential care facility, a patient's home, etc. This initiative is currently independent of the DHB or the Ministry of Health, both of whom declined support stating that it was impossible to implement. Now, of course, the DHB is discussing how they might integrate their systems with those of the RGPG! This technology has implications for the future monitoring of

- smart implants with location tracking sensors;
- patient vital signs anywhere in the community;
- personal defibrillators employing telemetry; and
- diagnostic devices that may interact electronically with healthcare information systems.³³

1.15 International Initiatives in Patient Safety

NZ is not unique in the world, failing to learn from medical accidents. In response to the UK Government's drive to develop a strategy for reporting, analysing and drawing lessons from accidents, The National Patient Safety Agency was formed in 2001. This agency sponsored 'The Design for Patient Safety Initiative', jointly funded by the [UK] Department of Health and the Design Council to provide recommendations for a designed programme of activity to reduce medical error. ³⁴

The report's authors discovered that

- *the NHS is 'seriously out of step with modern thinking and practice' on design, leading to avoidable risk and error;*
- *design practice and understanding is less advanced in the NHS than in other safety-critical industries;*
- *not only does the design of individual devices and products need to be improved, but also the way the NHS views the potential of design thinking and methods to help organisations as a whole; and*
- *single design initiatives have to be seen in the light of the 'big picture' of the healthcare system and how it relates to patients.*

The Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH), Nottingham Hub School of Electrical and Electronic Engineering, University Park Nottingham, has also addressed these issues, producing a number of excellent publications.

Whilst much guidance exists in theory, MATCH's interviews with the medical device industry have revealed a quite ad-hoc approach to user issues. ³³ Limitations from a small number of pilot interviews discovered that [N.B. amended syntax]

- *market push is the main driver rather than customer pull, so that the user needs are not prioritised as a central principle;*
- *the need for confidentiality results in early assessment iterations being conducted in-house e.g. on employees;*
- *serendipitous methods may be utilised to select users, e.g. 'trying out' of initial design ideas on acquaintances who are not in the intended age group for the innovation;*

-
- *advisory panels of clinicians (e.g. specialist physicians) were utilised instead of front-line users of the device (e.g. ward nurses) or hospital administrators;*
 - *there was difficulty in 'pinning down' of expert opinions, suggesting lack of skills in this area;*
 - *devices that worked in a hospital lab setting were not ergonomic in the clinician's working space, or well suited to a busy environment;*
 - *manufacturers pre-empted user requirements in the context of changing work practices e.g. increased the use of outreach teams (who would be involved in responding to alerts generated by monitoring devices, for example); and*
 - *manufacturers clearly identified the need for reducing time-to-market and lowering costs, highlighting help with complex regulations and conducting clinical trials as priorities, rather than improving approaches to user needs, i.e. they were not explicitly asking for guidance in human factors.*

1.16 Where is New Zealand in the Context of International Medical Device Development?

New Zealand does not have an international reputation or standing in the field of MD's and very few firms focus on devices that are Class IIa or higher. Those who do, manufacture a very limited range of products.

establishing a more vigorous and viable MD industry base may be difficult as NZ

- does not have the established foundation high tech industries in precision optics, integrated circuit or manufacturing and micro-machining in exotic metals, ceramics, etc; See Chpt 2
- lacks the innovation and incentives stemming from defense or aerospace industries;
- lacks the infrastructure to encourage synergy for technological developments; and
- finds it difficult to access key components to incorporate into high level technology.

There is also a high cost for a manufacturer developing higher class devices, as they require very rigorous QMS's that are expensive to maintain and beyond the capacity of the average SME. There is also a high direct cost for achieving compliance and IP – and the risk of having to defend IP if challenged in an international court.

For a NZ SME, the manager/owner has to balance their time/financial resources between innovating, managing and marketing and it is a rare individual that will be skilled in all of these fields.

Attracting highly trained staff with our relatively low wage structure is difficult and although many may choose to live in NZ for the lifestyle, attracting specialised staff will always be a challenge; ultimately we must create wealth by exporting goods and services to raise wage scales.

The drivers for a MD industry in NZ include

- an aging population;
- the burden of chronic disease including diabetes, arthritis, obesity and age related handicap;
- with a chronic current account deficit of around 9% of GDP, the need to economically diversify industry; and
- a challenging, interesting industry, to provide opportunities for our highly skilled graduates and keep them in NZ.

NZ appears to excel in innovative S/W developments and associated with emerging wireless technologies, there is the potential to develop unique solutions by capitalising on the need to service NZ's dispersed population. Developments could emerge from trials in test sites such as Rotorua, where the GP's have developed a unique wireless network accessing in excess of 70,000 persons living in the region. The opportunities to monitor and treat patients with remote sensors and drug delivery systems appears obvious.

There is the potential to tap into ideas for innovation and extract value from academic and other research establishments, health professionals and the health services if suitable organisational structures are created to support industry development. A radical change in culture would be required to make this a reality however.

There is a high commercial value in MD for NZ – with premium priced, small, high value items easily transported internationally, however it is difficult to service remote markets and we do have to contend with the tyranny of distance.

Although a great deal of attention has been applied to wheelchairs and 'standing' devices in recent years, design has not significantly influenced the market, with the exception of the spectacle frame industry.

Visual [and hearing] impairment affects 100% of the population - if they live long enough; familiarity neutralises stigma. How many spectacle wearers would consider themselves as a handicapped person? In fact spectacle frames have become a fashion accessory. On the other hand it is likely that hearing aids attract

more notice and comment, because they are less common.

See the Box below:

Assistive Devices

Assistive devices include "any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities" ³⁴

Note: Definitions:

Impairment – Reduced functionality [but that may not matter – if the impairment does not handicap the individual, for example it may not matter that a person cannot swim!]

Handicap – Unable to perform to a desired level of functionality.

Disability - A condition or function judged to be significantly impaired, relative to the usual standard of an individual or their group.

There are opportunities in the assistive device field where the compliance issues are not so onerous. ^F

Back injury from patient handling is of serious concern to the ACC, especially as the population becomes heavier and debilitated by conditions such as diabetes. Lifting patients weighing in excess of 250Kg for bathing, toileting and transport presents special problems, especially in their home. Modification for ceiling mounted gantry cranes, widening doorways and remodelling bathrooms may be prohibitively expensive and frequently cannot be justified if the resident has a poor prognosis. If the facility design restrictions are insurmountable, there is usually no choice but to transfer handicapped people into supervised care at greatly increased cost over that expended for home care. The lack of integration between the designs of each device is also a significant issue. For example power assisted hospital beds are commonly designed with the

F Classification of Assistive Devices

As most assistive devices are external to and disconnected from the body, they would be classified as Class A. If however they are complex devices, for example to assist with locomotion and requiring implanted electrodes, innovated from the peripheral nervous system, then the components would be classified as Class C devices.

mechanism under the bed and close to the floor. This prevents the protruding trolley base of a lifting hoist from cantilevering under the bed. Compromised handling of patients while bridging the gap between assistive devices may result in them being bumped or dropped, resulting in further injury. This area of assistive devices represents a major opportunity for innovation.

Regardless of the classification of MD's , there are special features in the design process that present a challenge. These special features of MD are discussed in detail in Chapter 2.

2. Special Features of Medical Devices

2.1 Introduction

The commercial success of a manufacturer hinges on successful New Product Development [NPD], whether it is to expand a product range, innovate, or to incorporate advancing technology. However the product development processes used within the medical device industry are generally more complex than those encountered within most commodity markets, due to the extent and depth of the regulatory environment.^{36,38}

In addition, by their very nature MD's are technology based. Within most SME's in NZ, the depth of technological expertise is insufficient to enable a development to be carried through to conclusion without external assistance. An innovative NPD frequently arises from an idea suggested by a [health-care] professional who is familiar with existing technologies. They recognise that an improvement in functionality would add significant value to a currently available MD, or that a procedure or test might be enhanced or facilitated by an innovation. Unless that professional is a multidisciplinary 'expert', the gap between the idea and the realisation of a NP must be bridged by significant changes to current practice.

All MD's must obviously function safely and reliably while being suitable for volume manufacture at the appropriate scale and conform to a variety of standards in design, production and quality management. Furthermore concepts of home healthcare and the 'expert patient' suggest the need for a more consumer centred perspective.³⁷ When considering the consumer a distinction must be made between Users and End-Users. End-users are patients, clients, and consumers for whom the device is intended or being used by.

See Box.

Users and End-Users

When considering the consumer a distinction must be made between Users and End-Users. End-users are patients, clients, and consumers for whom the device is intended or being used by. Users are professionals and lay people, who use devices for or on behalf of end-users. End-users can also be users, using devices on their own behalf. The important issue is that the recipient of the device should be fully represented in device development and evaluation. Therefore, both user and end-user information is crucial in medical device technology development.³⁹ A holistic perspective on medical device users is required for ultimate success.

2.2 Benchmarking – Best Practice

2.2.1 Traditional Product Methodologies

Benchmarking best practices is a process of continuous process improvement for an organisation including manufacturers. There are innumerable references available about the subject. Broadly the process may be broken down into fields such as

- strategy & Planning;
- organisation, teams & training;
- process;
- tools & methods for design optimisation; and
- technology – [incl IT]

An indicative summary of references to Benchmarking and Best Practice has been developed by DRM Associates and PD-Trak Solutions.⁴⁰

Their concept of benchmarking is illustrated in Figure 10.

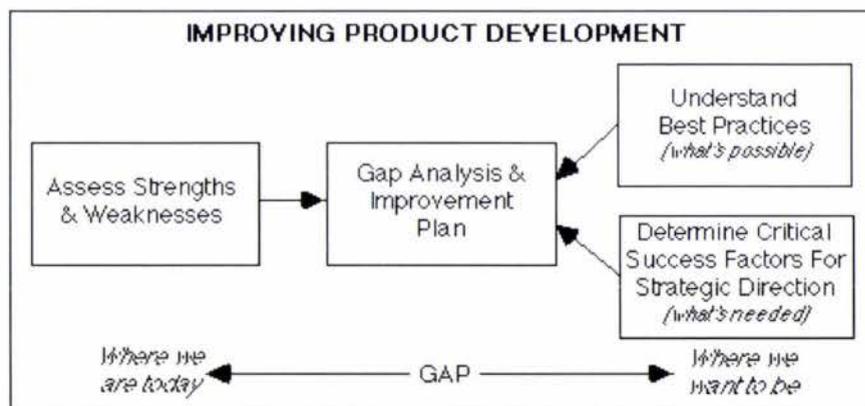


Figure 10. Improving Product Development

By focusing on the 'gap' between where the company is now and where it needs to be, priorities can be set for improvement.

Kenneth Crow, DRM Associates⁴¹ state that in conventional NPD's there is solid evidence to support the following success factors:

'The Number one success factor is a unique, superior and differentiated product' ^{41,42,43}

Superior products delivering real and unique benefits to users succeed far better than the 'me too' products with few elements of differentiation. The top 20% products are five times as successful as the bottom 20%.



Strong market orientation is critical

Market orientation includes a thorough understanding of the customer's needs and wants, the competitive situation and the nature of the market.

Do your homework

The steps preceding the actual design and the development of the product screening, market studies, technical feasibility assessment, product definition and building the business case are key factors for success.

Define the project early

Good definition includes specification of target markets, the product concept and positioning as well as product features and specifications.

A cross-functional effort is essential

Product innovation should be multidisciplinary, lead by strong leader-champions with top management support.

New product success is predictable

The most important criteria fall into three categories: product superiority, synergy with the company's resources and market attractiveness.

New Product success controllable

Quality of execution of the project is a key to success.

Speed is important! But not at the expense of quality

Speed may bring the product to market as #1 with less likelihood that the market has changed. Shortcuts may cost in the long run if specifications are not clearly defined then changed during development; product testing is inadequate, leading to product failure and recalls; there are inadequate resources for the project; or there is poor leadership.

Use a multistage, disciplined new product game plan

A formal 'Stage-Gate' is a solution proven by many firms to be a strong management technique.'

Note: Stage-Gates have been included in the Medical Device R&D Process; Chpt 4, Cl 4.3.1.

2.2.2 Critical factors in NPD

Many studies have been conducted over the years to identify the critical factors that discriminate between success and failure in NPD.^{44,45,46} They include management excellence/proficiency and customer value [understanding consumer needs]. Competition and timing of launch are less important if marketing is effective.

2.2.3 Recognizing Excellence

Promoting innovation in enterprises and spreading innovation excellence is one of the priorities of the new European Commission Innovation Action Plan. A so-called Trend Chart Policy Review workshop convened in October 2004 at Leiden, Netherlands, to identify the cases of excellence.....to develop a better understanding what 'excellence in innovation' exactly consists of and what makes a high performing innovator 'excellent'.⁴⁷

The EC initiative aims spread a culture of innovation among European businesses through the identification, benchmarking and dissemination of cases of innovation excellence. It hopes to inspire (potential) innovation leaders by learning from the best.

The workshop noted that:⁴⁷

'Identifying excellence also requires some indicators of the effects of innovation activities— e.g. growth in employment, market shares, profitability, as innovation is a means to an end and not a goal in itself. This profile of excellence can only be gradually built up after comparing sufficient companies that are regarded as good practice cases.'

With the population becoming increasingly aware of issues of the 'carbon footprint' and 'green

manufacturing' they are demanding products that have minimum impact on the environment. There will be increasing pressure on manufacturers to exercise social responsibility. In the not-too-distant future, environmentally benign manufacturing will become one of industry's greatest strategic challenges, not only from an engineering perspective, but from a business and marketing perspective as well.⁴⁸

New products in the field of MD's are not immune to these trends and in fact face challenges even beyond these issues, particularly with regard to community expectations of a high standard of health care until the end of an increasingly extended life.

2.2.4 Medical Product Methodologies

There is no argument that Best Practice for traditional methodologies is equally relevant for the NPD of MD's, however it is necessary to adapt most of the processes to

- adopt a user centred approach;
- adequately assess and integrate technical innovation during the development process; and
- factor in the regulatory environment.

In fact the emphasis of 'time to market' needs to be tempered if the project is likely to be jeopardised by rushing critical stages without compliance procedures being addressed, or there is inadequate testing or consumer evaluation at the prototyping stage.

Best practice for MD NPD challenges the boundaries imposed by the structure of many manufacturers. Traditionally an idea might have emanated from marketing, approved by the Board of Directors, a prototype made by R&D, tested, passed to manufacturing and marketed by the Sales Department.

Concurrent Engineering [CE]^G is a methodology that is being adopted by progressive manufacturers for the NPD process and has relevance to MD development.^{49,50,51}

CE forces developers to look at all aspects of design including quality, cost, manufacturability, user requirements and regulations right from the initial concept of design.⁵²

In CE a multidisciplinary team is assembled for a specified product which follows the development from inception to launch. The science behind a product will to an extent define the composition of the team,

G Concurrent Engineering (CE) is a systematic approach to integrated product development that emphasises the response to customer expectations. It embodies team values of co-operation, trust and sharing in such a manner that decision making is by consensus, involving all perspectives in parallel, from the beginning of the product life-cycle." - Definition European Space Agency.

however CE structures generally include expertise to advise on R&D, manufacturing, technical, marketing and compliance. Moving towards a user-centred approach advances this concept and technical input may also be provided by ergonomists, visual scientists or other specialist users or end-users.

It is generally accepted that these design teams be limited to less than 10 people and that the team approach should be 'round table' in nature.⁵³ The size may however be influenced by the complexity of the project. An improvement to an existing product will require less input and probably a less onerous compliance regimen, than a technologically innovative, breakthrough technology requiring multidisciplinary input.

An inter-disciplinary design team is difficult to manage efficiently. An effectively functioning team relies on a consensual approach to decision making, a willingness to concede personal aspirations and agreement to adhere to specifications. It is the author's experience that some professionals unused to this concept of work, are inclined to overlook vital elements of a specification in favour of an aesthetic or technological innovation that excites them. This results in wasted time, loss of productivity and it delays the development until they get 'back on track'.

It is also necessary to look beyond traditional methodologies of NPD because MD's frequently integrate technological innovations that require inputs of pure or applied research to define their application and determine whether they add value. This process may require testing at appropriate intervals to validate safety, performance or production factors – the Stage-Gate process. Depending on the outcomes, the development process for a NP may be disrupted until a particular technical issue is resolved. If this is unforeseen, requires significant resources, or unduly delays the process the project may be suspended. When the costs cannot be recovered in sales, a development may have to be abandoned.

2.2.5 The MATCH Project

Seminal work in the field of MD development methodologies has been performed by the Multidisciplinary Assessment of Technology Centre for Healthcare [MATCH] Team, a collaboration of five Universities: Birmingham, Brunel, Kings College London, Nottingham & Ulster.³⁹

An investigation of five MD companies was undertaken to explore their development processes for various classes of MD's, in relation to their size and organisational structure.

It was clear that the NPD procedures employed by the five companies have little in common. In general, perhaps not surprisingly, the larger companies appeared to have more a formal, stage-gated process with six or more stage-gates employed, while the smaller companies tended not to have such a rigidly applied process.³⁶

However the survey confirmed that all of the companies followed in broad terms the same four stages in the development process for MD's. These are four stages are

- proposal;
- preliminary investigation;
- detailed design & process development; and
- in use & follow-up.

These stages are briefly paraphrased.

2.2.5.1 Proposal Stage

'It is at this stage that a decision is made whether or not to proceed with the idea and to try to develop it into a product. Hence, this is one of the most fundamental stages for decision making, as any further development will cost substantial amounts of money which cannot be recovered until the idea becomes a marketable product.³⁶ Any money spent developing the idea from this stage onwards and subsequently filing the product prior to marketing will effectively be lost if a regulatory authority refuses marketing approval'.⁵⁴

2.2.5.2 Preliminary Investigation Stage

'Cross-disciplinary teams covering all aspects of the development, manufacturing and the marketing and sales processes are generally accepted as being the most effective.⁵⁵ The group is responsible for producing a more detailed design of the product, incorporating the developers skills and knowledge of materials relevant production techniques, the users knowledge of exactly how the device will be utilised including, for surgery procedures, means of insertion where applicable.

During this stage a more detailed market survey and implementation plan will need to be developed to provide information on both time scales for production and expected sales volumes'.³⁶

2.2.5.3 Detailed Design & Process Development

'Prototypes of the MD are built of sufficient detail and functionality to demonstrate to the development team, including Users and End Users what the outcomes of the development will be. Once consensus on the design has been reached, it must be frozen to enable process development

to occur. At this point some jigs and tooling may be developed to discover for example, if there are likely to be any manufacturing tolerance problems.

The compliance process must be strictly adhered to throughout the stages and any changes to the design or manufacturing processes documented'.

These documents will reside in the Technical File. See Chptr 4. QMS – Medical Devices

2.2.5.4 In Use & Follow-up

'When market approval has been gained, full scale manufacturing commences and cost models can be refined.³⁶ The market niche will define the methodology for tracking the product. Post market surveillance of disposables purchased by a Government Agency is simpler than monitoring complex diagnostic or assistive devices marketed through distributors dispersed throughout the world, however post market surveillance information must be sought reactively and proactively. Adverse incident reporting must be brought to the immediate attention of the central authority, regardless of the jurisdiction. On the positive side, customer feedback and satisfaction ratings may suggest design improvements for the next marque.

All five companies complied with FDA design control requirements that stipulate procedures such as design reviews and validation to be conducted during the development of a new product. These are laid out in the relevant section of the QSR regulations and supported by guidance documents from the FDA and GHTF'.⁵⁴

2.2.5.5 Summary Comments on the Study Outcomes.

A few pertinent points can be made about this study:³⁶

- *The most influential factor on management approval at the initial stage of the NDP pathway was generally availability of funding; external funding from business clients supplemented the smaller company's funds.*
- *Teamwork also seems to be an important aspect of the NPD process with smaller companies doing this as a matter of course, due to the inherently small number of employees.*
- *The smaller companies tended to produce the more innovative products. They were more likely to protect their intellectual property. Small companies may have the advantage of being closer to user needs and therefore be able to adapt to market requirements more rapidly.*

In order to examine the hypothesis that the device class that a given company produces influences its approach to NPD, then clearly more research is required. It is, however, safe to assume that such a relationship if it does exist is not a simple one and may have to incorporate other factors. These additional factors could include, as the length of time the organisation has been operational, how many products they have produced, how long products take to produce and if their ideas are customer or innovation led.

More work is needed to define what Best Practice is in the MD development field. It is a complex process and is driven by many factors that push the boundaries of conventional NPD's, but the most important are the processes that define the requirements of the user's and end-user's, then producing a functional, safe and compliant product'.

It was concluded that

- *embedding users and end-users in medical device development and evaluation should be a 'given' and a highly practical activity: currently this appears to happen in exemplary cases but is not a mainstream activity;*
- *the implementation of new methodologies inevitably implies challenges to the status quo and changes in current practice; and*
- *the indications are that an examination is required of the limitations of methodologies transferred from healthcare evaluation to medical device evaluation".*

2.3 Purchasing Decisions

Whereas, surgeons and other clinicians often influence the purchase of high cost items such as medical implants and expensive diagnostic and therapeutic procedures, nonclinical staff are often authorised to procure low cost/high volume items, especially disposables. Hence, the manufacturers of medical devices must be acutely aware of and responsive to the changes in dynamics that drive the market.

There has also been a shift in recent years towards professional management of treatment facilities. While a clinician's advice might be sought about the relative merits of a range of technologies on offer, the final purchasing decision is likely as not, made by a manager. The decision might be made on the basis of financial terms favourable to the institution, rather than strictly on clinical criteria.

Many companies face a dilemma in determining the necessary level of clinical evidence for a successful product launch. Empirical evidence, including that from interviews with industrial partners obtained as part

of the MATCH research programme, have shown that it was possible to obtain regulatory approval with quite limited clinical data (depending on device class and novelty) only to face difficulties in proving the advantages and cost efficiency of a new technology to potential purchasers. Many countries and insurance firms operate forms of health technology assessment and appraisal, for example the National Institute for Clinical Excellence (NICE) in the UK, advises government on the types of technology that should be used by and paid for under the National Health System (NHS). These agencies use healthcare economic modelling to ascertain the benefits to patients that a given technology can provide; this now in large measure, drives reimbursement.³⁶

It is imperative therefore that market intelligence about the operating environment for the proposed MD is gathered before the design proceeds very far. For example design and content of the labelling, training and instruction manuals should reflect the education and experience of the users, end users. The gender of the users, end users will influence the ergonomics of the design for issues such as reach and grip – even the colour scheme. Affordability and competitiveness must be gauged against funding structures of the target market, and provision made for educating the purchaser/s about the merits of the device, especially if they are likely to be clinically naïve.

2.4 Impact of Information Technology

Service contracts and software upgrades may further enhance the life cycle value of a system. With the advent of internet connectivity, error reporting and upgrades are the software industry standard within a license period. Generally firmware upgrades are not automatic, but MD manufacturers or their agents will frequently advise their clients when an upgrade is available. This is usually perceived by the client as adding value by extending the life of their MD's. There has been a perceptible shift away from dedicated software driven MD's, doomed to extinction within a short time period because of the rapid development of new technologies or advances in vision science.

In a cost-conscious environment, practitioners and organisations are favouring MD's designed with the expectation of an extended life, utilising flexible hardware platforms and supported by firmware and software upgrades. Purchaser loyalty may be sustained by regular servicing and at the same time there is an opportunity during a service call to enhance the functionality of the capital item and sell disposables.

2.5 Servicing and Support

Remote maintenance and servicing are commonly utilised in industry and in the energy sector where complex installations are constantly monitored for optimum performance. Even within the 'smart' or 'networked' home, Sun Microsystems Sun's [Java™](#) and [Jini™](#) technologies are enabling consumer white-

ware to perform additional functions such as purchasing, financial transactions and monitoring maintenance.

⁴⁸ Similar extensions in functionality for MD's are certainly feasible; however so far there does not appear to be a demand to incorporate features beyond the primary functions.

MD customers increasingly expect to pay for equipment based on uptime — the time equipment is available for use by the customer. Nowhere is this more important than with critical MD's such as radiological imaging and oncology systems. Delays in servicing a critical piece of equipment can be very disruptive and distressing to an entire organisation, especially it's patients and professional staff. Manufacturers must combine on-line, real-time repair information, inventory management, pricing, and invoicing with advanced logistics to equip service technicians with the right information and parts, at the right time and place, otherwise they lose the goodwill of their clients and market share. ⁵¹ Providing this level of service for a global market is a tremendous challenge, expensive and reflected in the initial purchase cost, plus the service contract and the cost of spare components.

2.6 Reliability and Safety

There is a higher bar set for reliability and safety of MD's than for any consumer product. This is because of the potential for a design defect or fault causing immediate or long term harm to a person exposed to, or dependant upon them.

Classification criteria for MD's are graded to reflect the potential seriousness of a failure of a product *in vivo* that may have been causing chronic harm over a protracted period when large numbers of these devices could have been dispersed throughout the world.

All potential risks associated with a MD are handled within a Risk Management regimen with mandatory recording of every step in the process. This applies not only to development and manufacturing, but also to Post Market Surveillance of the product. See C1 2.7 below.

Risks from a MD may include

- mechanical failure;
- electrical failure;
- release of toxic substances into the body or the environment;
- release of ionising or non-ionising radiation [including EMC]; and
- microbial contamination, etc.

The compliance regimen for managing risk is discussed in detail within Chapters 4 & 5.

2.7 Postmarket Surveillance Studies ³⁸

'FDA may order manufacturers to conduct postmarket surveillance studies to gather safety and efficacy data for any Class II and Class III device

- *the failure of which would be reasonably likely to have serious adverse health consequences; or*
- *which is intended to be implanted in the human body for more than one year; or*
- *which is intended to be a life sustaining or life supporting device used outside a device user facility.*

Manufacturers must, within 30 days of receiving an order to conduct a postmarket surveillance study from FDA, submit, for approval, a plan for the required surveillance. The FDA may order a study for up to 36 months. Any longer period has to be mutually agreed upon by the manufacturer and FDA. If no agreement or a longer time period can be reached, then a dispute resolution process is to be followed.

After receiving the manufacturer's proposed plan, FDA has 60 days to determine if the person designated to conduct the surveillance is qualified and experienced, and if the plan will collect useful data that can reveal unforeseen adverse events or other information necessary to protect the public health'.

To recall devices involves tracing them, not just to upgrade software as discussed above, but to be able to trace a single defective component anywhere in the world. To achieve this objective requires a highly structured Quality Management System [QMS] integrated with a Customer Resource Management system [CRM]. See Chptrs 4, 5, & 6.

2.8 Device Tracking ³⁸

'FDA has the discretion to order manufacturers of certain types of Class II or Class III devices to initiate a program to track their medical devices down to the patient level.

The types of devices subject to a tracking order may include any Class II or Class III device

the failure of which would be reasonably likely to have serious adverse health consequences; or

which is intended to be implanted in the human body for more than one year; or

which is intended to be a life-sustaining or life-supporting device used outside a device user facility.

In addition, patients receiving a tracked device may refuse to release, or refuse permission to release, their name, address, social security number, or other identifying information for the purpose of tracking.'

2.9 Research Data from Intelligent MD's

Although ethical and privacy issues must be addressed, [ethical approvals obtained] there is the potential for the use of the internet monitoring to 'data mine' patient international databases, to statistically analyze data for example and to raise the alarm about adverse reactions or to flag epidemiological trends. Third party service industries or medical researchers could perform this function just as readily as the manufacturer of the MD and has the potential to be a very powerful research tool.

2.10 Commercialisation scenarios

2.10.1 Protection of intellectual property

Intellectual Property Agreements [IPA's] or Non-Disclosure Agreement's [NDA's] appear to be widely used in NZ as a means of rapidly protecting IP, long before the technology has been completely defined. They have the advantage of simplicity and no cost; no legal input is required. As they are often signed at an introductory phase in a negotiation, it is the author's experience that the process has the effect of declaring the basis of the relationship; it is a formality but also trusting by revealing confidentiality.

Patent protection is of little value if the technology field is very dynamic. With advanced technology products involving 'blue sky' research, the development may evolve beyond the terms of the patent specification, even before it is marketed. It is almost inevitable that the time to market in NZ for a NPD is delayed because of the current development environment.

There are special issues about marketing in the US. The US Patent Office is completely overwhelmed as companies and individuals file for more and more patents. Currently there are delays of up to six years before publication, plenty of time to establish a market, then find that the product is in contravention of a prior right. As was expressed in Knowledge @ Wharton in 2006: ⁵⁶

'Some bad patents are being granted, and some companies are taking advantage of legal uncertainty to essentially impose a tax on innovation by threatening patent litigation.'

Yet not all companies that seek to enforce patents -- even those that acquire the patents from the original inventors -- are 'patent trolls.' Patents mean different things in different industries. For example, pharmaceutical and semiconductor companies use patents in radically different ways,

even though both depend on them'.

Patent risk uncertainty and/or search costs raises transaction costs for follow-on development. As the ultimate arbiter of a patent argument is the courts, any NZ manufacturer has to factor into any decision to market a product in the US, whether they are prepared to face a legal process!

In low cost, developing economies there is little respect for IP and inadequate legal redress available to prevent infringements. In mature markets, regardless of the justice involved, it is frequently impractical to protect a company's IP when the challenger is a large multinational with unlimited resources.

Even if the manufacturer files a Patent Co-operation Treaty [PCT] and defers the cost of filing in principle international markets for a period of 18 months, it is still a significant cost [from \$9000] for a start-up company in NZ.

Ultimately filing an international application in an English speaking country may cost up to \$3500; in a non-English speaking country, \$7000+. The decision about which countries to file in must consider:

- the size of the potential market, &
- the likelihood of a sales or manufacturing competitor in that market initiating an IP challenge.

2.10.2 SWOT [§] analysis

Value assessment for MD's is a complex task and developing products or investing in this sector can be daunting process. How can you make them to cost and specification? In late development, what is your best strategy to gain evidence? At launch, what will be your most effective way of providing evidence of value for reimbursement assessment? And for products already in the market, how can you best re-enter the regulatory cycle? ³⁴ 'Picking a winner' has to be measured in terms of the time and funds required to navigate the regulated pathways from concept to mature product, versus a return that may be difficult to predict compared to pharmaceutical products. ³⁹

A SWOT analysis provides a tool that might be usefully applied to the cost/benefits of investing in patent IP and in fact progressing with a development at any gate. This expenditure might be balanced by investing instead in alternate resources for the advancement of the product development. Protection might be achieved for example by investing in R&D to make the MD extremely difficult or expensive to reverse engineer.

This situation presents some real difficulties. In early development, for example, how do you pick winners 5-10 years out? Inevitably, this uncertainty impacts upon many innovative products and technologies in

§ Strengths, Weaknesses, Opportunities and Threats

some or all of the following ways

- longer time to market and to patient benefits;
- higher costs for both manufacturer and healthcare provider;
- greater commercial uncertainty and lower unit sales; and
- increased rate of commercial failure and missed or delayed opportunity. ⁵⁷

2.11 Marketing

2.11.1 Introduction.

Selling a traditional product to a consumer is generally a one step process – the buyer makes a buying decision, arranges the finance and the deal is done.

Rarely when selling a MD is the process so simple. There are two component's to the process.

Who is:

- The user or end-user? See Cl 2.1
- Going to fund the MD? See Cl 2.3

Complicating the issue further is the question of whether public or private funds are involved, government policies, the constraints on marketing or advertising and disposing of waste or recycling.

2.11.2 Community perceptions/expectations

Society expects that medical specialists and hospitals will utilise the latest technology and that it will be used for their treatment, sometimes whether or not it is appropriate to do so! This boosts sales for MD's, even if it is wasteful of health resources, but then the utilisation of the equipment is another issue! Capital items in consulting rooms, operating theatres and treatment facilities are universally underutilised, since it is not feasible to operate clinics outside of daylight hours, frequently because of staffing issues.

There is an understandable desire by the public to be able to directly access technology instead of travelling to a specialist centre for treatment. There are many examples of communities forming Trusts to purchase specific instrumentation for their local facility, however they would not under any circumstances contribute to a centre of excellence elsewhere in the country, even if it made the purchase of superior technology possible. It is not of course in the interests of vendors of MD's to discourage community initiatives. An

example is the current discussion about Positron Emission Tomography (PET) and associated structures.^H

If there is a need for more PET scanners, they should be clustered near a Cyclotron, rather than proliferating cyclotrons that are very expensive and require radiation proofed facilities.

Wherever continuing care or repeat treatments are involved, there is a community pressure to be able to access a local facility. Never mind that for all smaller towns and areas of low population density, it is clearly impossible to provide tertiary services at the 'back door'.

Specialist staff are of course required to operate and interpret the outcomes of investigative procedures. These overheads must also be factored into the purchase as well the problems of obtaining staff at a time of a man-power crisis.

It is extremely unlikely that any NZ company would become involved in the development of such equipment such as tomographer's, because their development would require resources that are unavailable in this country. However community expectations are a significant driver of sales for MD's up to approximately \$100K, especially for the private specialist sector. Patients are generally willing to pay for private investigative procedures, especially when they are subsidised by private, government or company health insurance.

2.11.3 Government Policies

Preventative medicine is increasingly promoted by government programmes to keep people healthy, diagnose medical conditions earlier and maintain them in the care of primary health practitioners and out of expensive secondary and tertiary hospitals.

One way of achieving these ends are screening programmes e.g. diabetic and cervical screening. These programmes generate markets for specific devices, usually office based, but incidentally increasing demand for secondary services, albeit at an earlier and less expensive stage. An example is diabetic screening when a fundal camera and associated software and computer system is required, costing approximately \$70,000. As the pictures of diabetic retinopathies require expert interpretation, accredited practitioners are funded by the programme to take the photographs and read them, thereby paying off the capital investment.

Colleagues have become aware from presentations at continuing education meetings of incidental pathologies revealed by the photos and realise the advantages of providing this service to their patients. They in turn have purchased a camera without the expectation of government funding or involvement in a

H. Limitations to the widespread use of PET arise from the high costs of [cyclotrons](#) needed to produce the short-lived [radionuclides](#) for PET scanning. The half-life of Fluorine-18 (F-18) is 110mins.

screening programme.

In some countries, for example the UK, independent organisations such as National Institute for Health & Clinical Excellence [NICE],⁵⁸ provide advice about the use of new and existing medicines, treatments and procedures.³⁷ As those who spend the health dollar become increasingly accountable, marketing to Government Agencies, whether it is to NZ District Health Boards, or the drug purchasing body Pharmac, is going to become increasingly fraught and less profitable. Time taken to prepare presentations, evidence of compliance, guarantees of service and delivery of disposables at a fixed price, etc, will be demanding.

Government policies effectively ration services, whether they be surgical procedures, delivery of drug therapies, or provision for extramural community therapists. Demand for the limited services may influence expenditure on MD's.

2.11.4 Demographic and Epidemiological Trends

An affluent, physically inactive, aging or obese society develops congruent diseases. The prevalence of these diseases influences decisions about the purchase of MD's for treatment and diagnosis.

2.11.5 Professional Politics & Culture

The evolution of professions from guilds over the last century has seen a great deal of politicking to protect the patch of the traditional practitioner. This has largely centred around 'patient safety' issues, whereas it is usually [unstated] about the threat to their livelihood. The respect held by the population for the surgeon/physician was well founded as they were highly trained individuals, however as their functions have become increasingly classified, measured and superceded by technology, there has been a development of scientists, professionals and technologists to perform sub-specialty tasks. NZ is more advanced than in many countries in adopting sub-specialists into their health system and the evolution of Nurse Practitioners and Optometrists licensed to use a limited range of therapeutic drugs are examples of this trend. To carry out their role for diagnosis and treatment they require a range of MD's. This presents new market opportunities for the manufacturer.

Demography of professions differs between countries. For example in Europe there is vigorous opposition to change in the ophthalmic professions because of a surplus of Ophthalmologists, particularly in Germany and France. By some estimates there are as many as four times the number of specialists per head of population as in New Zealand. This has resulted in strong lobbying by the medical profession to prevent Optometry from becoming established in those countries. Because of their background and training, Ophthalmologists emphasise medical and surgical services, rather than the visual sciences, reducing the demand for

instrumentation to support the assessment of visual performance.

The result is that the distortion in the practitioner mix biases the sale of certain classes of MD's in these countries. In fact it may also restrict the range of services available for some patient groups because of the unavailability of sub-specialties. The author has a number of patients in Europe who return periodically to NZ for treatment, or travel to London, their nearest centre.

Culture, relationship between the sexes and religious mores, also influence examination techniques and procedures in many countries. It is not very many years ago that the writer faced difficulties examining religious orders that had starched wimple's that projected forward, preventing them from placing their head on a chin rest or against the back of an instrument.

Particularly in developing countries parallel systems may operate with traditional practitioners working alongside 'western' qualified professionals. As these professionals extend their skills and breadth of practice, their demands for supporting diagnostic and treatment equipment will increase. As the service market matures in these countries with increasing expectations and affluence of the population, a demand for MD's will create sales opportunities.

In summary, medical professionals are often the users and more often than not, the end-users of MD's. They purchase equipment to use in their offices, or directly or indirectly influence expenditure in secondary and tertiary facilities. Their training, professional environment, attitudes and culture, all influence their purchasing decisions.

2.11.6 The Competition; Price Sensitivity

If the technology is unique and remains so due to strong IP protection, complex engineering or hidden technology, MD's may enjoy a period on the market without competition. Subsequently if the technology becomes 'mainstream', it may attract the attention of a manufacturer outsourcing to a low cost economy, to bring to market a competitive device.

A MD may incorporate significant technical improvements over the features offered by their competition. If seen by the users to offer considerable added value to their practise, price may not be particularly sensitive. On the other hand if a MD is just one of many on the market with similar functions, price often becomes a deciding factor in a purchasing decision.

2.11.7 Marketing by Functionality

Grouping MD's by function provides one means of developing a marketing strategy. The divisions are

- assistive devices;
- diagnostic and treatment devices; and
- disposables.

2.11.7.1 Assistive Devices

Generally classified as Type 1, assistive devices are usually marketed to end-user's [the person with an impairment] or to user agencies who allocate, hire, or lease the device to the end-user. Examples of funding agencies in NZ to end user's are the Royal New Zealand Foundation of the Blind [RNZFB] & the New Zealand Disabilities Resource Centre [NZDRC].

Some agencies and merchandisers supply the public directly and of course so do Pharmacies, by far the largest purveyors of disposables and pharmaceuticals. Some Pharmacies differentiate their business by stocking assistive devices and as they promote themselves as dispensers of professional advice, there is considerable goodwill and public trust in their expertise. This may be enhanced by providing their staff with specialist product training, very evident with cosmetics and hair products, but equally valid with assistive devices.

Advertising targeted to user groups like the elderly through Newsletters such as Age Concern, may be considered.

2.11.7.2 Diagnostic and Treatment Devices

Office Based Devices

Medical graduates in NZ are increasingly choosing a specialist medical career, rather than General Practice. The reasons for this are not within the scope of this paper, however specialist practice requires diagnostic and treatment not needed by GP's. This would suggest that the market for Office Based Devices [OBD's] will expand.

Many other allied health professionals use MD's in their office including Optometrists, Ophthalmologists, Nurses, Dentists, Podiatrists, etc.

An increasing percentage of the population are seeking 'alternative, natural & holistic' health remedies and with the adoption of these therapies, there is a market for MD's associated with their treatments.

There is an increasing emphasis by regulatory authorities on 'Good Practice'. This might be related to

recording investigations, but it also implies carrying out a range of tests, appropriate to the person's age, medical status and health. This trend creates a demand for sophisticated MD's to conduct the tests.

Practitioner 'image' and 'fashion' trends are also significant drivers for purchasing decisions. A practitioner may be well qualified and competent to make clinical judgements based on patient history, experience and basic physiological and physical tests. MD's may not be required for this process, however as previously discussed (CI 2.11.2), patient's expect to be examined with the latest technology and if the environment and MD's in the facility are dated, they are less likely to have confidence in the clinician.

Influential early 'adopters' may start a trend for other practitioners to follow. For example a ground breaking procedure reported at a conference may result in rapid acceptance of a new technology into mainstream practice – eventually becoming 'good practice'!

Professional training establishments influence new graduate preferences for equipment. Continuing education, publications and peer pressure also increases awareness of new technologies.

Hospital Based Diagnostic Services

The inadequacies in public health services are reflected in the demand for private health based insurance services. These have developed around primary and secondary health, rather than tertiary hospital therapies involving high value MD's and requiring considerable infrastructure support.

Medical Specialists have considerable influence in the purchasing decisions made in these private establishments. As these institutions are far less constrained by bureaucracy and more by commercial imperatives, purchasing decisions are made far more expediently.

In the public sector the business case to purchase a MD is placed on a 'wish list' and it may be years, if ever, before the money is allocated for the acquisition.

Disposables

Disposables dedicated for use with a diagnostic device, may during its lifetime, provide more profit than the original device. Generic items such as dressings, hypodermic syringes or specimen pottles are highly competitive items and when purchased in volume, there is little opportunity for the manufacturer to set a realistic price for a product. In fact, what is a market today, may be gone tomorrow when another manufacturer undercuts a traditional supplier. What often maintains the market is a 'smart' feature that differentiates the product to add value. It might be, for example a superior adhesive on a dressing that resists moisture, is anti allergenic and can be removed without discomfort.

2.12 International Marketing & Distribution Issues

2.12.1 International Marketing

International marketing of medical devices is generally conducted through medical device suppliers with international connections, who may network with selected companies in a state or country. The manufacturer may assist by representing the equipment personally at trade displays in association with the distributors at educational conferences.

Distributors can be supported by the principal's website, with profiles of the distribution and service network, FAQ's, technical product and related health information. Recent advances in customizable, on-demand, Customer Relationship Management [CRM] programmes for Small & Medium Business offers exciting possibilities to manage international marketing when integrated with a Website. Enquiries are logged automatically and convenient response menus allow them to be managed efficiently, at least the routine responses. Some of these programmes [e.g. ZoHo CRM] are free for up to three users and offer all of the features of their commercial cousins.⁵⁹

2.12.2 Inventory

Distribution of stock is always an issue for a country as distant from international markets as New Zealand. The weight and bulk of lower cost MD's may preclude them being routinely transported by airfreight. For high value items where freight is a relatively low proportion of the total value, airfreight may still be a viable option.

Establishing inventory levels for a distant and hopefully expanding market may initially be problematic if there is a lead time of many months for some manufactured or imported components.

2.12.3 Servicing & Upgrades

In common with most electronic consumer goods, there is now a tendency to replace modules of medical devices, rather than repair individual components. Trouble-shooting is facilitated when a faulty module can be identified and recalibration may not be an issue if the module is pre-calibrated.

As the distribution network extends, the problem for the manufacturer is what policy to adopt for a spares inventory; where it should be sited and the number of spare components to hold in stock.

Most MD hardware cannot be upgraded and it is not in manufacturers interest to do so if further marques are planned. However upgrading firmware and software is a distinct possibility and may be facilitated by internet access to the control software through a laptop or the patient data management system.

2.12.4 Training of Servicing Network

Organisations marketing medical devices generally have well established networks to service other products they sell. Establishing a unique servicing network for the NZ manufacturer should not be necessary.

However specific product knowledge will be needed and this will possibly require visiting each distributor, considering cultural and language barriers and establishing personal relationships.

Rapid communication about servicing problems may be facilitated by the use of emails and reference to secure sectors of the Website.

2.12.5 Development of Tutorials, Manual & Website

Good design should allow for intuitive operation that requires little explanation.

Particularly for diagnostic MD's, the instructions for operating the machine must be supplemented with detailed protocols about interpreting the data outputs.

Due to the complexity of many of these devices, continuing education seminars are frequently conducted by the manufacturer's representatives and local practitioners are invited, whether they have purchased the equipment or not. They are encouraged to attend because doing so qualifies them for 'points' to maintain their continuing education quota. It also provides an opportunity for collegiality and up-skills the attendees about the potential of the equipment, enabling them to refer to their colleagues with confidence.

Practitioners are tutored to understand and administer the tests, analyse the results and inform the patients about the implications of the findings.

Operating instructions for the MD should be provided as a 'hard-copy' manual, possibly on a CDROM and maybe incorporated into a limited access, user's area of the website. All documents must be in the local language in addition to English and reflect the user's culture.

Providing appropriate diagnostic results is a multi stage process from some MD's. For example an initial screening programme may provide preliminary data. These may suggest to the practitioner a more specific programme to differentiate the results as an enhanced, indicative output that provides a diagnosis.

Normative data from a representative patient sample may be preloaded to provide references for the practitioner of any departure of the test from the normal. More intelligent machines may even 'learn' from the expanding database providing ever more accurate and representative data.

With this summary of the special features of MD's, the challenges of their development will now be addressed in Chapter 3.

3. Challenges in Medical Device Development

3.1 Introduction

The challenges inherent in the development of MD's are largely proportional to the level of the general classification as a MD. As previously noted in Chapter 1, simple non-invasive devices require less regulation and need to meet less onerous standards than more complex, potentially invasive devices.

For all but the simplest MD's it is likely that during the development, some R&D will be required to overcome a technological problem. This may be beyond the expertise of the developer and require the services of an expert in the field. If this subcontract is foreseen, there is funding available and the time to completion is factored into the schedule, the business plan will not be affected. If however it is not anticipated and it involves pure research with an uncertain outcome, it may jeopardise the whole programme.

Locating solutions is easier with the advent of 'Googling', however there are barriers to accessing technology, especially from government research and academic institutions in New Zealand.

The present culture of such organisations is unsupportive of entrepreneurial activity; they generally avoid direct participation, but may license or sell IP to the developer. As the principle generators of innovative technology and to facilitate MD development in NZ, this inflexible attitude must be overcome by adopting new business metaphors and business models.

3.2 Sharing IP - Technology Transfer

Lawrence & Bryan refer to the gaps between scientific discovery and technological innovation as having process and cultural dimensions.⁶⁰ They note that the process of science is first and foremost discovery and technology the application of knowledge to useful objectives. Cultural differences are shaped by technical understanding, community expectations and business forces; bringing together scientific, business and government people whose outlooks, specialised knowledge and professional languages are distinctly different.

NZ is not unique in experiencing problems with establishing dialogue between manufacturers and academia. At the [Australian] Prime Minister's Science, Engineering and Innovation Council - Third Meeting held on Friday 25 June 1999, at Parliament House, Canberra, it was noted that:

'A major source of difficulty for entrepreneurial scientists is the lack of recognition given to academics for commercial endeavour. Recognition and promotion in universities is still very much based on the system of peer review and accreditation through journal publications (the 'publish or

perish' phenomenon). However for academics involved in business activities, there is a commercial imperative not to publish results and thus no academic recognition comes from the work. Similarly, due recognition is not accorded academics for time spent working in industry and thus mobility between academia and industry is stifled. There needs to be a new system which rewards entrepreneurship as well as scholarship (patents as well as publications) and which recognises the value of mobility between academia and industry'.²⁴

There has been some progress as linkages are being fostered by universities through organisations such as Auckland UniServices Ltd. They are actively involved in the formation of new businesses based on research developed at the University of Auckland. And Canterprise Limited, the commercialisation and knowledge transfer company of the University of Canterbury, has supported a number of significant commercial developments.⁶¹

The Crown Company Monitoring Advisory Unit [CCMAU] reports that since 1992, all Crown Research Institutes [CRI's] have restructured and repositioned themselves, invested heavily in science assets and new facilities, and made considerable investments in new science capabilities. The nine CRI's now have total assets of \$483.5 million and employ 4,166 staff members, of whom 3,360 are engaged in research and research support (as at 30 June 2006).⁶²

However several representations by the author to the board and executive of the CRI – Industrial Research Ltd [IRL] within the last two years, inviting them to participate in joint venture activities have been ultimately declined, despite initial enthusiasm. The problem for NZ, MD developers is that purchasing advice or technology from IRL at a high hourly rate is daunting, especially if they are reluctant to provide a fixed price. Adopting a business model that could offset R&D against future profits is a pragmatic solution, but clearly too risky for them to contemplate.

Several IRL commercial ventures have failed in recent years and the considerable financial losses have forced them to review their management and objectives; their CEO has resigned and restructuring has created new businesses. Clearly IRL are having problems adjusting to commercialism and their response is probably a carry over of the attitudes from before the decade of reform of the public sector that began with the election of the Fourth Labour Government in 1984.

A thesis by Poletti [2000] focuses on the metaphor of business as it was evidenced during reform of the publicly funded science institutions in the period 1992-1995.⁶³ With the importation of the idea of business in the public sector, a fairly precise set of associations was invoked, chief amongst them efficiency, market forces or disciplines, competition, entrepreneurialism and success: such terms are frequently encountered in the descriptions of the reform years and as frequently rejected by critics of that process.^{64,65,66}

The intention throughout the reform period was to induce a change in understandings of what matters, of what is valued, and the business metaphor has been a key agent in that change. ⁶⁷

The assumption appears to have been made in the reform process that the new understandings will simply replace the old ones, without struggle or modification. Work in organisational analysis however suggests that where there is a mismatch of perceptions, a variety of responses may occur, from buffering strategies to decouple core activities from those at the boundary and to defuse conflict, to reject and to actively remodel.

68,69,70

3.3 Availability of Components

There is great potential to develop MD's in N.Z. around novel uses of existing technology available from overseas suppliers. International companies supplying the technology however, appear to anticipate only the modest market represented by NZ, rather than looking forward to a global market. Despite initial interest, the author has found to his cost on several occasions that technology promised has ultimately not been forthcoming. Despite a trip to the OSRAM factory in Germany to confirm the specifications of the component, they ultimately reneged on their agreement to supply. Without the component, a flat panel fluorescent lamp known as a PLANON, the MD development project could not proceed to the original specifications and a considerable proportion of the nearly \$200,000 investment has had to be written off. A further concern has always been that as no alternative comparable component was available from another manufacturer, the project and financial viability of the company would have been jeopardised should OSRAM stop manufacturing, significantly change the specifications, or fail to supply for whatever reason. These fears have of course been confirmed by OSRAM's unprofessional behaviour.

A further example relates to a component required for another project which was discussed with a US company for nearly five months. Their Vice President, Sales, was finally embarrassed to admit that he had been overruled and they would not supply, because they were overcommitted with US Defence contracts.

With a limited budget, the SME faces a considerable obstacle when accessing high priced components in what, for the suppliers, is a very limited production and marginally profitable. For example the OSRAM Planon was expected to cost nearly \$1000/unit and as they intended to manufacture production runs of 12,000 units, the 100 units they agreed to supply the author for an initial run would have been added to the end of the cycle. Investment of \$100,000 for 100 units represents a very considerable sum for a modest enterprise, months before the first sale could be anticipated.

Uncompetitive costing of manufactured components by a monopoly manufacturer is a further risk. If initial estimates are used to justify a design concept and are subsequently found near the end of the design process

to be significantly lower in value than the final quotation, a redesign process may be necessary using alternate processes and materials. The resulting expense and delays may be significant and jeopardise the viability of the project.

In hindsight these supply risks should have been factored into the profile of these developments. See below:

3.7 Risk Management.

In future all developments undertaken by the author will utilise technology available from a range of sources, together with materials that will perform a similar function, even if less desirable in terms of form and design qualities.

3.4 Specialised Manufacturing

The manufacturing technologies required for lower classification devices are frequently less sophisticated than for more invasive products. However particularly for implanted MD's, issues such as miniaturisation, materials, reliability, finishes, toxicity, sterilisation and packaging must be factored into component selection and availability.

3.4.1 Miniaturisation

Putting aside the more esoteric developmental technologies such as IC manufacture that will probably never eventuate in NZ, or unique and specific nanotech developments such as NCD wires,⁶¹ external assistive devices such as hearing aids and implants have to be as small as feasible.

Processes such as electro-forming, ceramic injection moulding, photo etching and laser machining of light gauge parts, are but some of the many machining options that are inaccessible within NZ.

3.4.2 Materials

Materials in contact with body fluids and tissues must be inert and meet rigorous standards of quality, particularly for stressed components such as prostheses.

Machining and fabricating inert, tough metals such as titanium present particular challenges for NZ manufacturers. Sintered ceramic components, injection mouldings in ceramics and specially formulated polymers are available from selected manufacturers in Europe and the USA, but are not manufactured in, or are difficult to source from NZ suppliers.

3.4.3 Toxicity

The Removal of Hazardous Substances [RoHS] and Waste Electrical and Electronic Equipment [WEEE] Directives [2002/95/EC](#) on the restriction of the use of certain hazardous substances in electrical and electronic equipment and [2002/96/EC](#) on waste electrical and electronic equipment are designed to tackle the fast increasing waste stream of electrical and electronic equipment, complementing European Union measures on landfill and incineration of waste. Increased recycling of electrical and electronic equipment will limit the total quantity of waste going to final disposal. Producers will be responsible for taking back and recycling electrical and electronic equipment. This will provide incentives to design electrical and electronic equipment in an environmentally more efficient way, which takes waste management aspects fully into account. Consumers will be able to return their equipment free of charge. In order to prevent the generation of hazardous waste, Directive 2002/95/EC requires the substitution of various heavy metals (lead, mercury, cadmium, and hexavalent chromium) and brominated flame retardants (polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)) in new electrical and electronic equipment put on the market from 1 July 2006. ^{71,72}

The list of banned substances has become so numerous and their application so complicated that major manufacturers have compiled tables for the guidance of their engineers. Typical of these is the The Ericsson lists of banned and restricted substances. ⁷³

For some products where the properties are dependant on banned substances, for example crystal glass containing lead, exemptions have been granted or are being considered. ⁷¹

Probably the most contentious of the RoHS directives has been that relating to the removal of lead from solders used for printed circuit boards (PCBs), since all available scientific evidence indicates that the lead used in printed circuit board manufacturing and electronic assembly produces no significant environmental or health hazards. ⁷⁴ The re-formulation of solders has increased the melting temperature of the solders, heat stressing components, requiring new packaging and special assembly techniques. **See Appendix 1**

3.4.4 Certificates of Compliance for Outsourced Products

With the uncompetitive NZ manufacturing economy especially for consumer products, manufacturers are increasingly outsourcing components from low wage economy countries such as China, Malaysia and India. Inevitably questions will arise with regard to the reliability of the certificates of compliance accompanying components supplied from such sources. For critical components Classified IIb and above, it may be necessary for the MD manufacturer to visit the suppliers to determine first hand that the specifications of components are being adhered to. Even the ingredients of paint could be an issue. [Note: The many recalls

over recent months of children's toys manufactured in China and painted with paint containing lead.]

Audits of suppliers are mandated with the SOP11 'Inspection & Test Status'.^{75,76,77,78,79} To achieve EU specification or FDA approval the manufacturer has no choice but to implement a QMS that will stand up to audit.

3.5 Time to Market

Time to Market is the period from conception to the point of sale and is an extremely important issue for consumer product industries where fashion and 'fads' influence demand; products are outmoded quickly and product cycles may need to be only months apart.

It is proposed only to specify impediments to achieving a short time to market for a MD as there are many issues in common between domestic or consumer products and MD's, including principles such as

- establishing clear goals for the project;
- motivating and selecting 'teams';
- scoping the tasks;
- risk management;
- use of advanced software for digital mock-ups and simulations; and
- rapid prototyping, etc

Beyond well documented management methodologies that address these principles, for MD manufacturers there are the delays imposed by the rigours of administration of the QMS and compliance issues. [See Chpt 4 QMS – Medical Devices](#)

With little experience of the MD development process, SME's with few in-house resources, find it virtually impossible to anticipate all of the steps in the development process and even if they do identify them, they lack the time necessary to complete them.

There are further sources of frustration for NZ MD developers. Particularly for complex technologies, the average SME is obliged to subcontract facets of the development outside their technical competence, such as software or optical design.

Delegating key elements of the process to a subcontractor contributing components or services to the project

leaves the developer vulnerable if delivery promises are not kept. Specialists are frequently over-committed and set their own time-lines. Many component manufacturers have only a trade background and function with only very basic management systems; they simply cannot accurately predict deliveries. They may argue that their existing clients take precedence over their manufacturing or time resources. They frequently shift their priorities to meet the expectations of another client pressuring them. However as they gain experience with a new client and appreciate the potential market for a new product, they are more likely to meet performance deadlines.

3.6 Differentiated Markets

Demand for a MD in a particular country will be influenced by many factors including

- health standards;
- affluence;
- regulation;
- education;
- endemic disease; and
- civil unrest, etc.

In many countries there are parallel systems operating with traditional practitioners working alongside tertiary qualified professionals. With increasing affluence, the population may demand and can afford a higher standard of service; there is consequential shift in expectations about access to MD's. It follows that as professions evolve, extending their skills and scope of practice, their demands for supporting diagnostic and treatment equipment increases.

Examination techniques and procedures may be modified to conform to cultural and religious mores. The evolution or introduction of a professional within a country may also be influenced by professional politics and culture as referred to in Chpt 2.11.5.

Regulation of health professionals to some extent follows the development of the society. To achieve a license to practice implies professional competence gained by qualification, training, experience and maintained with continuing education. With exploding health budgets and a shortage of Physicians, governments are seeking less treatment options by relegating treatment to less expensively trained health professionals than medical practitioners. Quality assurance programmes imposed by regulation and funding

audits, together with evidence based medicine has also an [unintended] consequence; reliance less on professional judgement and more on analysis and measurement. This results in a demand for MD's, analytical technology and computer based diagnostics.

For the MD designer issues of practitioner competency, profiles of potential users, tailoring the technical specifications to the professional user, all present ergonomic design dilemmas. Training and operating manuals have to be written, not only in different languages in a culturally sensitive manner, but must be pitched at the level of understanding and training of their professional users.

See [Chapter 2. Special Features of MD's](#)

3.7 Risk Management

Management of risk during the development of consumer products is essential, as the developer may

- incorporate untried or unproven technologies leading to a 'dead-end' project;
- fail to achieve compliance with untried or unproven technologies;
- discover that the technology proves to be costly to take to market or the selling price of the product will be too high;
- discover the market is not large enough;
- be under-capitalised;
- lack the resources to adequately market the product;
- face a challenge from the holder of threatened intellectual property;
- be delayed releasing a product so that the technology is superceded before it reaches the market;
and
- be defrauded by an employee or subjected to industrial espionage.

The liability of the manufacturer of consumer products may be restricted to the consumer protection legislation of the country of distribution, however the transport cost incurred for a recall, repair/modification and redistribution and perhaps compensation of internationally distributed products could be ruinous. There is also the loss of creditability of a brand that the company suffers and may never be redeemed.

Enterprise Risk Management [ERM] presents special challenges for the for the MD developer because there is the additional risk of a product recall due to a component failure, or because the device caused unforeseen harm to consumers. The additional costs of litigation if it eventuates because of harm, particularly in the USA, could cripple all but the largest organisation.

In response to the harm caused by the MD's in the past, the regulatory environment has evolved and adds another layer of business and financial exposure, as do issues of efficacy, pricing, and availability. In the USA the Food & Drug Administration, Department of Health and Human Services/Office of Inspector General, [FDA] may order manufacturers to conduct postmarket surveillance studies to gather safety and efficacy data, requiring the manufacturer to track their product down to the patient level. See Chpt 2 – Special Features of MD's.

3.8 Risk Intelligence Defined

Deloitte Risk Intelligence takes risk management to a higher level to create a new view of and approach to risk. Essentially, a Risk Intelligent approach⁸⁰

- *recognizes and manages the full spectrum of risks the organization faces;*
- *minimizes “siloes” behavior that can obscure an integrated view of risk;*
- *allocates proportionally more resources to the most strategic and pertinent risks;*
- *considers effective risk management to be an organization-wide responsibility and competency;*
- *anticipates and prepares integrated responses to risks;*
- *manages risk with a view toward maximizing the upside of strategic decisions while minimizing the downside; and*
- *acknowledges the need to take intelligent risks to create value.*

Deloitte also further points out that risks may be unrewarded, but there are also rewards to be gained from taking 'smart' risks.

'Unrewarded risks can result from actions either internal or external, including the following:

- *compliance with the dictates and guidelines of the Securities and Exchange Commission, Department of Justice, European Medicines Agency, Japanese Ministry of Health, and*

numerous other regulatory agencies;

- *accelerating global regulatory activity regarding consumer privacy and the inappropriate exposure of consumer information;*
- *issues of product safety that go beyond regulatory criteria (sometimes only discovered when the product has reached market);*
- *security breaches and IT system failures;*
- *inadvertent exposure of intellectual capital; and*
- *cost and availability concerns.*

Examples of rewarded risks in the life sciences include the following

- *products that prove to be more effective than anticipated: This is seen in Phase III trials, or even as the result of post-marketing studies, and it leads to gaining unanticipated market share upon launch, sometimes resulting in demand outstripping supply;*
- *competitors' products fail or develop safety issues: Same result as above;*
- *products are approved earlier than expected or in more markets (U.S. and global): While this happens infrequently, it does occur, particularly where there are active consumer advocacy groups who pressure for early review; and*
- *production yield improves; or the manufacturing process improves potency or significantly lowers production costs.*

Biotech manufacturing processes are especially unpredictable; however, the experience curve generally points to improving yields and

- *additional indications are discovered during pre-approval or post-approval clinical activities: For this to be legitimate, additional clinical trials need to be run, but this has become common recently with biotechnology drugs. (There are also downside risks associated with this if these trials have not yet been run and there is word-of-mouth demand. This results in unrewarded regulatory risks associated with allegations of off label promotion.)'*

By releasing restricted quantities of the product in NZ & Australia initially, there is the opportunity to gain

market approval, discover where any risks may lay and limit the liability to an environment that is less litigious than the USA.

3.9 European Union - Risk Analysis for Medical Devices

3.9.1 Risk Analysis Standards

The European Union has developed new medical device standards Risk Analysis. ⁸¹

- EN1441:1997 Medical devices – Risk analysis,
- EN60601-1-4: Medical electrical equipment Part1: General requirements for safety 4: Collateral Standard: Programmable electrical medical systems, &
- ISO 14971-1:1998 Medical Devices - Application of risk management to medical devices

However these standards have now been Harmonized under the Medical Device Directive (MDD) and apply to MD's sold in Europe.

EN ISO 14971:2007 - Medical devices - Application of risk management to medical devices was staged 28th Feb 07 and has superceded EN ISO 14971-1:1998, together with the two other standards above. EN ISO 14971:2007 may also be used for meeting requirements in other countries including the USA, Australia N.Z, the Far East and Canada.

3.9.2 Steps in Risk Analysis

The Risk Analysis should be a living document throughout the design cycle and into production. ⁸¹ The steps of risk analysis are:

3.9.2.1 Identify the potential hazards using cross functional teams that might include engineering, R&D, clinicians, marketing, users, regulatory, product safety engineers, manufacturing, etc.

3.9.2.2 Define the probability and risk of each hazard using either a bottom-up Failure Mode and Effect Analysis or a top-down Fault Tree Analysis.

3.9.2.3 Determine which hazards have risk levels that require mitigation.

3.9.2.4 Mitigate the hazards. Check to ensure no new hazards are generated. Continue to mitigate hazards until the risk level is low enough to be acceptable.'

Quality Management Systems are the key to mitigating risk. Their development in a novel form for use by SME's is discussed in detail in Chapter 4.

4 QMS – Medical Devices

4.1 Introduction

Before classifying a new product as a MD, it is necessary to demonstrate **conformity** with the essential requirements and to enable conformity to be verified.⁸²

As discussed previously, the higher the classification for the MD, the more stringent the requirements for a QMS to achieve conformity. The specifications of the device define which standards are appropriate. For example a MD that has Radio Frequency emissions or requires sterile packaging, will invoke different criteria for conformity.

All MD's must be manufactured within a **Quality Management System [QMS]** to enable conformity to be verified within the directives of **93/42/EEC**.¹

For a SME in NZ, the high costs and demands on time to establish and maintain a QMS is significant and beyond the capability and ability of most.

Possible choices for the manufacturer to achieve conformity include

- institute a AS/NZS ISO 9001:2000 QMS;
- subcontract the manufacture of the product to a AS/NZS ISO 9001:2000 compliant organisation;

I Recommended compliance routes:

Class I

1. Hold a Technical file*
2. Self-Declaration of Conformity according to Annex VII.
3. Observe provisions of the procedures referred to in Annex IV, V or VI of 93/42/EEC for "sterile" or "Measuring" function devices.
4. Apply CE mark.

Class IIa & IIb

1. Hold a Technical file* Obtain ISO 9001:2000 certification.
2. Audit by notified body according to Annex II. Apply CE mark.

Class III

1. Hold a Technical file* Obtain ISO 9001:2000 notification.
2. Audit by notified body according to Annex II.
3. Product Dossier Exam by notified body according to Annex II. Apply CE mark.

*Technical File Content:

General product description Design drawings, methods of manufacture and diagrams of components and sub-assemblies, Description and explanation of above-mentioned drawings and diagrams. Result of risk analysis and list of standards referred to in Article 5 of 93/42/EEC, applied in full or in part, and descriptions of the solutions adopted if not applied in full. Description of the methods used if the device require sterility. The results of the design calculations and of the inspections carried out. If the device is to be connected to other device(s), proof must be provided that it conforms to the essential requirements when connected. The tests reports and where appropriate, clinical data in accordance with Annex X of 93/42/EEC. The label and instructions for use.

-
- license the product to another, for the purposes of manufacture and marketing; or
 - utilise an advisory agency providing subcontract QMS services. [Such an agency does not exist in NZ - yet!]

4.2 Manageable Software Solutions

Many international organisations specialise in establishing and operating comprehensive QMS programmes that do not readily scale to the resources of a NZ SME.⁸³

Recent software advances enable considerable automation of the QMS process once the systems and templates are in place. The structure discussed below offers an advantage over traditional paper based systems because it allows SME staff to operate as a 'virtual organisation' from any internet connection in the world.

It is feasible for any organisation to utilise templates adapted to meet the requirements of the ISO. This chapter discusses how these templates offer a solution, supplemented with standard office, CAD and browser programmes plus a range of other tools to achieve an adequate depth of management control.

Fundamental to the QMS are concepts such as Manufacturing Resource Planning [MRP]⁸⁴ or Enterprise Resource Planning [ERP],⁸⁵ however most MRP and ERP programmes are complex, have high time overheads and are unsuitable for SME's. Document control is essential for compliance, but extraordinary vigilance is required to ensure a manual system is maintained and attention to such detail has a low priority for most organisations. The complexity of R&D and the compliance process can be overwhelming. Nevertheless planning software can be of enormous assistance.

A number of software programmes have been considered for incorporation into the QMS described below, encompassing planning, management and accounting control.

They include

- Groove [Microsoft Office 2007];
- Servage – one solution;
- DBA Manufacturing; &

-
- Mindjet MindManager Pro.

Groove synchronises all other computers in the network and if granted permission by the administrator, allows encrypted access by participants to selected folders and files. ⁸⁶

A number of specific features of Groove are ideally suited for a QMS, including the permissions function and the file management folder. The Log attaches a unique change note and version number to each file. See Figure 11. [Note the random number attached to the file and the version number associated with the current entry.] Groove accesses files as attachments, or from within the programme, imposing document control. For example, when generating a Purchase Order, only the latest component drawing should be accessible to avoid errors in the specification. Drawing documents are held in the Technical File of the QMS, while Purchase Orders must also relate to Bills of Materials [BOM's] and quotations. Groove links the BOM, Purchase Order and Component Drawings as the specification for an **Audited Supplier** to manufacture the components at the quoted price.

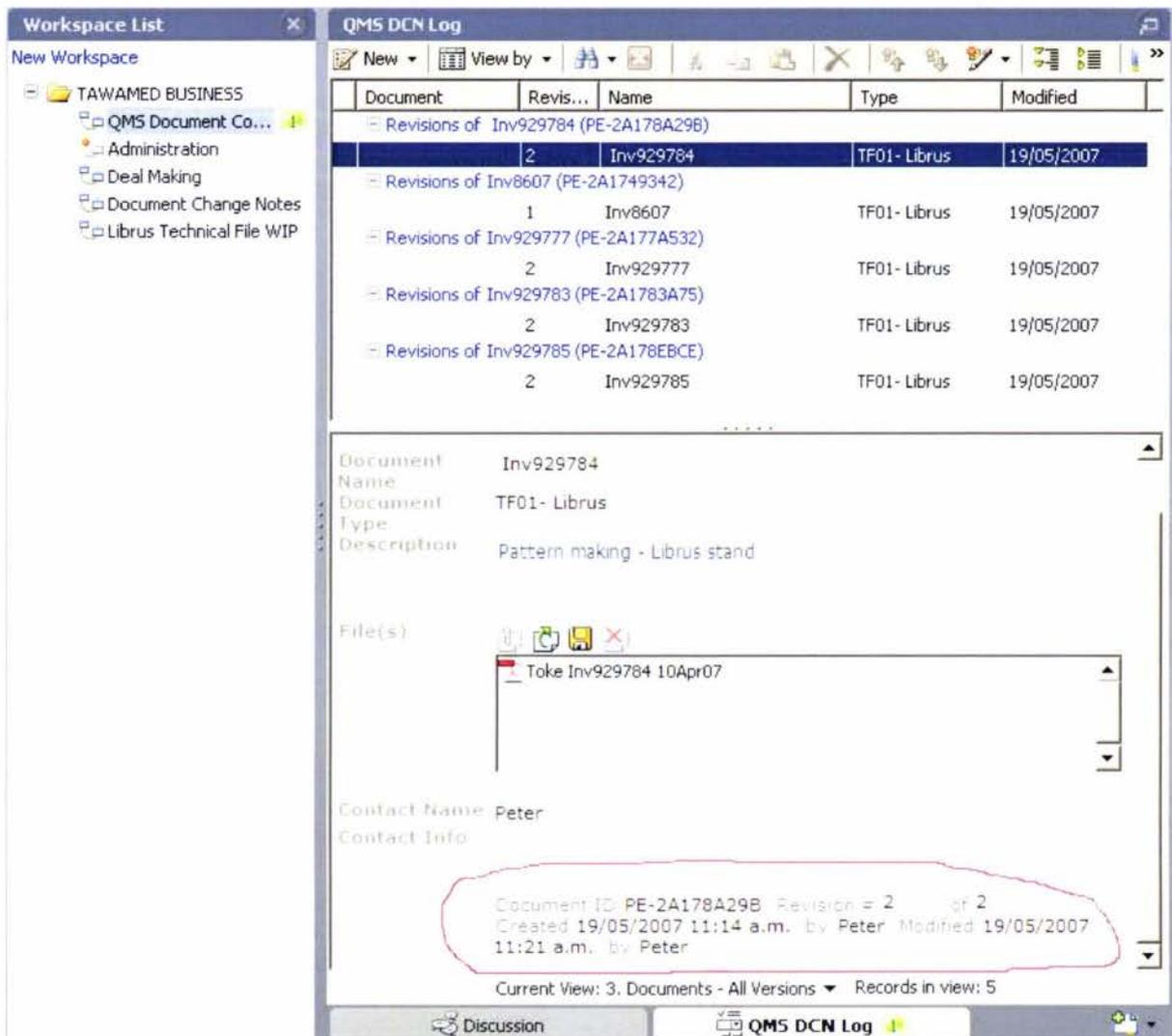


Figure 11. Document Control Within Groove

A number of other programmes apart from Groove were investigated including **Microsoft Office SharePoint Server 2007** ⁸⁷ and **o3Spaces Workplace**. ⁸⁸ The former programme must be licenced, while O3Spaces Workplace is available free for a limited number of users, is integrated with the OpenOffice Suite and – quote:

“O3Spaces Workplace brings document management and document collaboration features to OpenOffice.org / StarOffice and Microsoft Office, including real-time version control, check-in/check-out and document security.” ⁸⁸

After considerable thought it was realised that any of these options simply added complexity, without adding

functionality. Conceptually folders, files and tree structures are now intuitive and duplicating them in a secondary programme simply to impose document control, made no sense. Provided control could be imposed on existing structures, ISO constraints could be achieved.

Also with broadband internet connection and the remarkable drop in cost and increase in availability of data storage, now in remote servers, novel solutions have become feasible. The Servage programme is an example.

Servage – one solution is a server that provides for a modest monthly fee, a wide range of facilities, including: ⁸⁹

- 360 GB Web Space
- Transfer more than 3 Terabyte per month!
- Unlimited FTP Accounts
- 1000 MySQL Databases
- PHP v 4.4.4 & 5.2.1
- Hotlink Protection.
- PhpMyAdmin
- ImageMagick Support
- Ruby on Rails
- Password Protected Directories
- FTP Access
- FTPS (Encrypted FTP)
- GD Support
- Microsoft Frontpage Support
- WAP Enabled
- mod_rewrite Enabled
- CGI/Perl
- Python Support
- ionCube Loader
- CURL Enabled
- Webbuilder Software Included
- Netpbm Support
- Wildcard Domains
- Full .htaccess Support
- Shockwave & Flash
- XML Support
- EXIF Support
- SSI Support
- Private CGI-BIN

With password protected directories it is feasible for all or part of the Repository of the QMS to reside on the server as a public or secure knowledge library and be accessed through the Servage WebDrive S:\. This drive appears in the folder structure of the computer, can be accessed along with any other drive and backed up onto an external hard-drive.

The Website for TawaMed will front the server, providing public access to product information. Suppliers of TawaMed will be permitted to access familiar folders and files in the deeper layers via a time-limited password. Suppliers may download FTP drawings and documents; the problems of transferring large files associated with 3D drawings are thereby overcome.

Only 'frozen' CAD files will be accessible to suppliers through their FTP folder along with the corresponding Purchase Order and BOM. This will ensure that only the current specification will be manufactured at the quoted price. These documents will also be lodged in the Technical File [Red] Folder as well as the TawaMed Server QMS folder.

Effectively the Website, the FTP division and the public and secure Knowledge Library of the Repository on Servage will constitute a ExtraNet of the TawaMed Business Server. See Figures 13, 16 and 19 below.

As the Servage is accessible from the remote site administered by the Account Manager, she can integrate the quotation and ordering process of the manufacturing programme with the manufacturing and funding costs together with the current accounts for TawaMed.

The password protected directory and file logging system in the Servage facility is so versatile that it has been decided that the additional layer of Groove is unnecessary; even email & SMS facilities are provided, so communication can be maintained between staff members while online.

DBA Manufacturing is a comprehensive accounting and manufacturing programme that can be operated by an Accounts Manager, remote from the Administrator. Integration between the processes of the Accounts Manager and the Administrator is achieved by exchanging or exporting/importing spreadsheets or backup files by logging onto the WebDrive S:\.

In this manner, Supplier documentation that pertains to manufacturing technology, audit reports or IP for example, can be left in the repository [see below] to be included in the technical file on the Server, while quotations are duplicated in the DBA programme with the BOM data.

DBA is scalable and may be used only for MRP, but as it is integrated with an efficient accounting

programme, it is intended to be used to administrate the financials and manufacturing for the enterprise.

Mindjet MindManager Pro⁹⁰ is a mind mapping programme has been used to structure the QMS described below. Many other commercial and open source mind mapping programmes are available.^{91,92,93} However Mindjet MindManager has many features that are admirably suited to the operation of the QMS. For example a plug-in allows the Mind map to exactly reflect the folder/file structure to which it has been hyperlinked. Simply by activating the update button, the latest versions of the files are reflected in the map. Even videos, 3D images and spreadsheets can be embedded while maintaining the currency of their file versions.

4.3 The QMS

4.3.1 The QMS Structure

The Administrator accesses QMS files from a specific folder on the C:\ drive. The folders associated with the QMS root directory are shown on Figure 12 below.

The folders include

- Servage backup - regularly backed up files from the S:\ drive, in addition to the backups of data files;
- QMS document library - not all available QMS draft documents are required for each Technical File [TF] and management system, but still held as draft documents in the library;
- QMS help - including tools like DBA Manufacturing support, Groove support and the Mind Manager Dashboard;
- Repository. N.B. Although all repository documents are relevant to the project, only those that directly relate to the design and function of the MD will ultimately be included in the technical file. 'Frozen' Repository files may be reflected onto Servage; in effect as a Extra-Net for access by suppliers

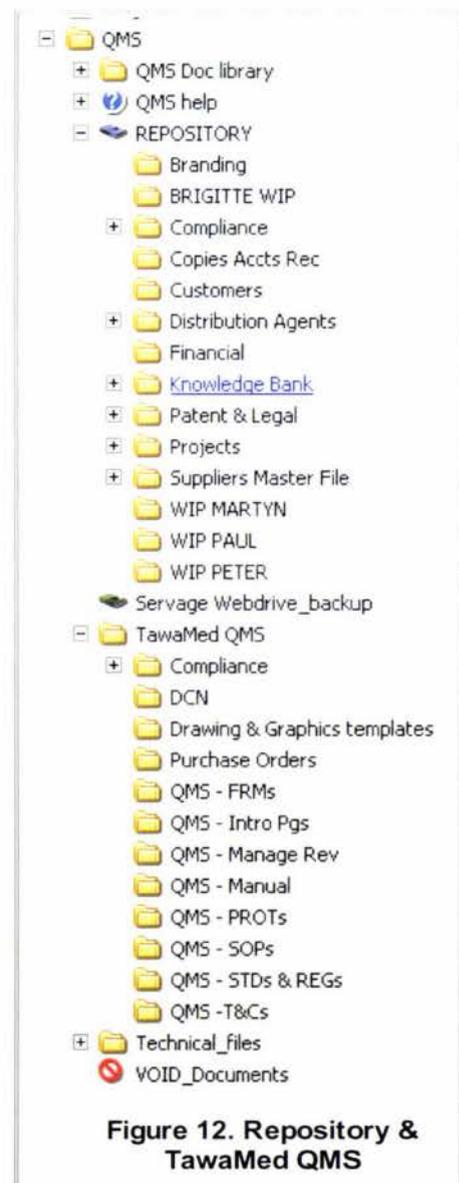


Figure 12. Repository & TawaMed QMS

through a FTP folder;

- Work in Progress [WIP] folders include documents that may be ultimately included in the technical file.
- TawaMed QMS - Documents including

Compliance

Standard Operating Procedures

Document Change Notes [DCN]

Introductory pages

Drawing & Graphics templates

Management review

Purchase Order Log

Standards & Regulations

Forms

Terms, Conditions and Agreements.

Manual documentation

Technical Files - Including all technical files apart from those held in WebDrive S:\ such as document control notes and in DBA for BOM's and supplier's documentation.

Protocols

For details of the Technical File, see Chpt 5.12, Fig 33

and;

- **Void documents** - All documents no longer current are removed from circulation and stamped 'void'.

The Communication Structure of the QMS system is illustrated below in Figure 13.

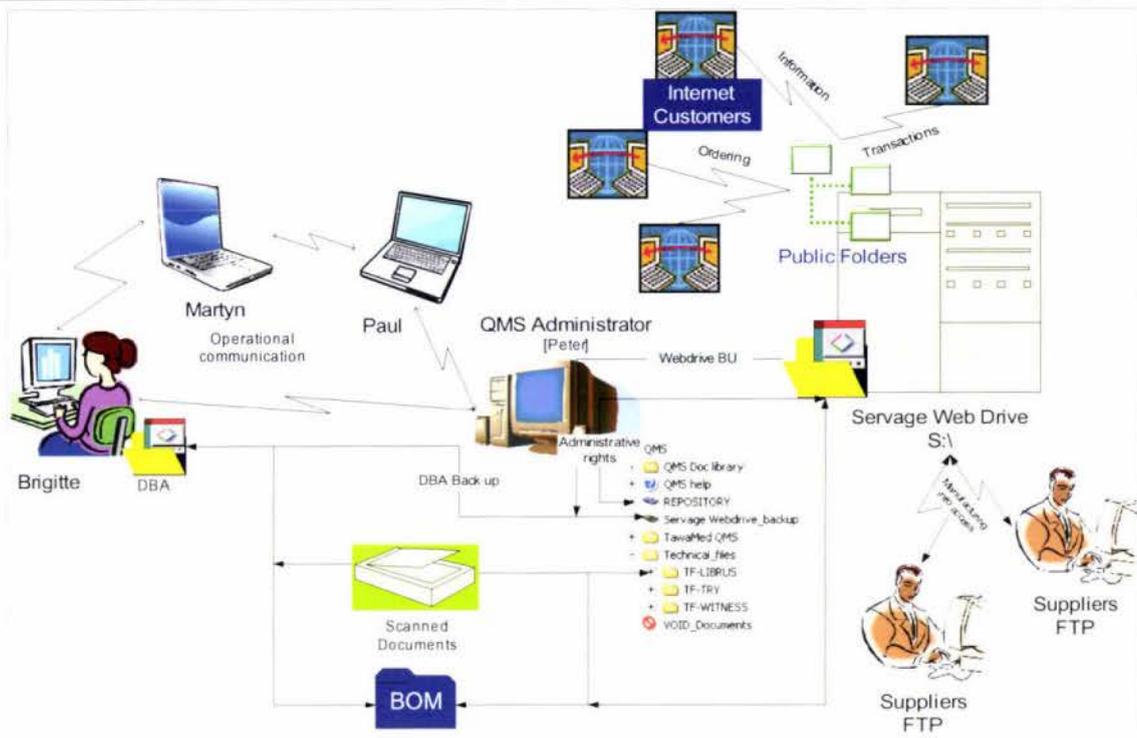


Figure 13. The QMS & Servege Communication Structure

4.3.2 QMS Documentation

The Tawa Medical Holdings Ltd Quality Management System comprises four levels of documentation:

4.3.2.1 Level 1: The Quality Manual (Document #: QM 01)

This document describes the Quality Management System including the Company policy, objectives for establishing and maintaining product and customer service, together with quality assurance. In addition it explains how the requirements of various standards and regulations are addressed and satisfied.

The manual is structured to correspond with clauses 4.1 through 8.53 of **ISO 13485:2003** and the corresponding clauses of **ISO 9001:2000**.^J

In addition it addresses specific requirements of the European Communities Medical Devices Directive **93/42/EEC**. See **Appendix 1** referencing each clause and subject area to the appropriate Standard Operating Procedure (SOP).

^J Many changes to ISO standards have been made in the last 7 years relating to MD design. The 9000 series has been consolidated in ISO 9001:2000, ISO 13488:1996 and ISO 13485:1996 has been superseded by ISO 13485:2003. A number of others relating to risk management have been withdrawn. The summary in Appendix 3 is not exhaustive, but represents many of the major changes.
See Appendix 3 – Recent changes to ISO Standards.

4.3.2.2 Level 2: Standard Operating Procedures

(Listed in Procedures Manual - Table of Contents Document #SOP00). These procedures are not product specific.

Section A comprises those SOP's, corresponding with clauses 4.1 through 8.53 of **ISO 9001:2000** and **ISO 13485:2003**, that are applicable to Tawa Medical Holdings Ltd's business. [See Appendix 3 – Recent Changes to ISO Standards].

Section B comprises those SOP's associated with the regulatory requirements of the European Medical Devices Directive **93/42/EEC**. However the details of the SOP's are beyond the scope of this paper. The emphasis is on Quality Records; if records are inaccurate and/or incomplete, an audit of the QMS will fail and the company will be considered non-compliant. [See Appendix 4 – Quality Records.]

A log of the SOP's is below. See Figure 14.

4.3.2.3 Level 3: Product Specific Documents

Typical documents are:

| | |
|--|--|
| Material Specifications | Packaging Specifications |
| Engineering Drawings for components and product assemblies | Instructions For Use |
| Bills of Materials | Product Testing Reports |
| Label Artworks | Risk Analysis Reports |
| | Manufacturing Process Validation Reports |

These documents are either contained within, or their location referred to, within the relevant product Technical File. [See **TF-LIBRUS** – See Sec 5.12]

| SOP # | Title | Current Issue | Date | Forms Used (FRM) |
|-------|--|---------------|----------|------------------|
| 01 | Management Review | 1 | 22/5/07 | |
| 02 | Organization | 1 | 22/5/07 | |
| 03 | Quality Planning | 1 | 22/5/07 | |
| 04 | Particular System Requirements for Medical Devices | 1 | 22/5/07 | |
| 05 | Contract Review | 1 | 22/5/07 | |
| | | N/A | N/A | |
| 07 | Document Control | 1 | 22/5/07 | 06, 07 |
| 08 | Purchasing Control | 1 | 22/5/07 | 10, 11, 12, 21 |
| 09 | Product Identification and Traceability | 1 | 22/5/07 | 13 |
| 10 | Inspection | 1 | 22/5/07 | 09, 11 |
| 11 | Inspection and Test Status | 1 | 22/5/07 | |
| 12 | Non-Conforming Product | 1 | 22/5/07 | 22, 23 |
| 13 | Corrective and Preventive Action | 1 | 22/5/07 | |
| 14 | Complaint System | 1 | 22/5/07 | 04, 05 |
| 15 | European Advisory Notices and Recalls | 1 | 22/5/07 | 19 |
| 16 | Handling, Storage, Packaging and Despatch | 1 | 22/5/07 | 20 |
| 17 | Quality Records | 1 | 22/5/07 | |
| 18 | Internal Quality Audits | 1 | 22/5/07 | 15, 16, 17 |
| 19 | Training | 1 | 22/5/07 | 08 |
| | | N/A | N/A | |
| 21 | European Vigilance Reporting | 1 | 22/5/07 | 14, 18 |
| 22 | Communication with the Notified Body and the Competent Authority | 1 | 22/5/07 | 01, 06 |
| 23 | Post Marketing Surveillance | 1 | 22/5/07 | 02, 04, 05, 14 |
| 24 | Technical Files | 1 | 22/5/07 | |
| 25 | Declaration of Conformity | 1 | 22/5/07 | |
| 26 | Language Translation Management | 1 | 22/5/07 | |
| 27 | ID of Reg Requirements of non EU | 1 | 21.12.06 | |
| 28 | FDA Labelling Management | 1 | 21.12.06 | |
| 29 | FDA Med Dev Reporting | 1 | 21.12.06 | |
| 30 | FDA Voluntary recalls-Corr & Removal | 1 | 21.12.06 | |
| 31 | FDA Mandatory recalls | 1 | 21.12.06 | |

Figure 14. Standard Operating Procedures (SOP) Log

4.3.2.4 Level 4: Forms and log sheets.

These are used to record data related to the manufacture of the product and the control of the manufacturing process, together with the maintenance of the quality system. The document numbers are prefixed FRMXX. The detail of the forms is beyond the scope of this paper.

A log of the FRM's follows on the next page. See **Figure 15**.

Master copies of Levels 1 and 2 are included within the RED binder held in the company office and

maintained by the Administrator.

Master copies of the documents associated with Level 3 are held between the Technical File, [TF – LIBRUS], Repository [S:\QMS\Repository plus C:\QMS\Repository], DBA Manufacturing [Master programme on Accounts Manager computer in Tawa – Back Up copies in Servage WebDrive Workspace plus TawaMed Business Server]. Hard copies are included in the RED folder held in the company office and maintained by the Administrator.

Documents for **Work In Progress** are found in the **WIP** folders; Peter WIP, Paul WIP, Martyn WIP & Brigitte WIP, in the Servage WebDrive Workspace and TAWAMED Business Server.

Figure 15. Forms (FRM) Log

| FRM No. | Title | Current Issue | Date |
|---------|--|---------------|----------|
| 01 | Communication with the Notified Body and the Competent Authority - Log Sheet | 1 | 22/05/07 |
| 02 | Post Marketing Surveillance – Contact Record Sheet | 1 | 22/05/07 |
| 03 | Not Used | 1 | 22/05/07 |
| 04 | Customer Complaint Form | 1 | 22/05/07 |
| 05 | Customer Complaint Form Log | 1 | 22/05/07 |
| 06 | Document Change Note | 1 | 22/05/07 |
| 07 | Document Change Note Log | 1 | 22/05/07 |
| 08 | Training Record Form | 1 | 22/05/07 |
| 09 | Receiving Inspection Log | 1 | 22/05/07 |
| 10 | Purchase Order Form | 1 | 22/05/07 |
| 10a | TMH Purchase Order1 | 1 | 22/05/07 |
| 11 | Approved Suppliers List | 1 | 22/05/07 |
| 12 | Purchase Order Number Log | 1 | 22/05/07 |
| 13 | Product Identification List | 1 | 22/05/07 |
| 14 | Initial Incident Report Form | 1 | 22/05/07 |
| 15 | Internal Audit Schedule | 1 | 22/05/07 |
| 16 | Internal Audit Report Form | 1 | 22/05/07 |
| 17 | Internal Audit Report Form Log | 1 | 22/05/07 |
| 18 | Final Incident Report Form | 1 | 22/05/07 |
| 19 | Initial Recall Report Form | 1 | 22/05/07 |
| 20 | Inventory Record | 1 | 22/05/07 |
| 21 | Supplier Evaluation Form | 1 | 22/05/07 |
| 22 | Product Reject Form | 1 | 22/05/07 |
| 23 | Product Reject Form Log | 1 | 22/05/07 |
| 24 | Supplier Audit Schedule | 1 | 22/05/07 |

4.4 The MindManager Dashboard

To organise the large amount of paper and significant number of files involved in the QMS, a Dashboard has been developed using Mindjet MindManager referred to above. See Figure 16.

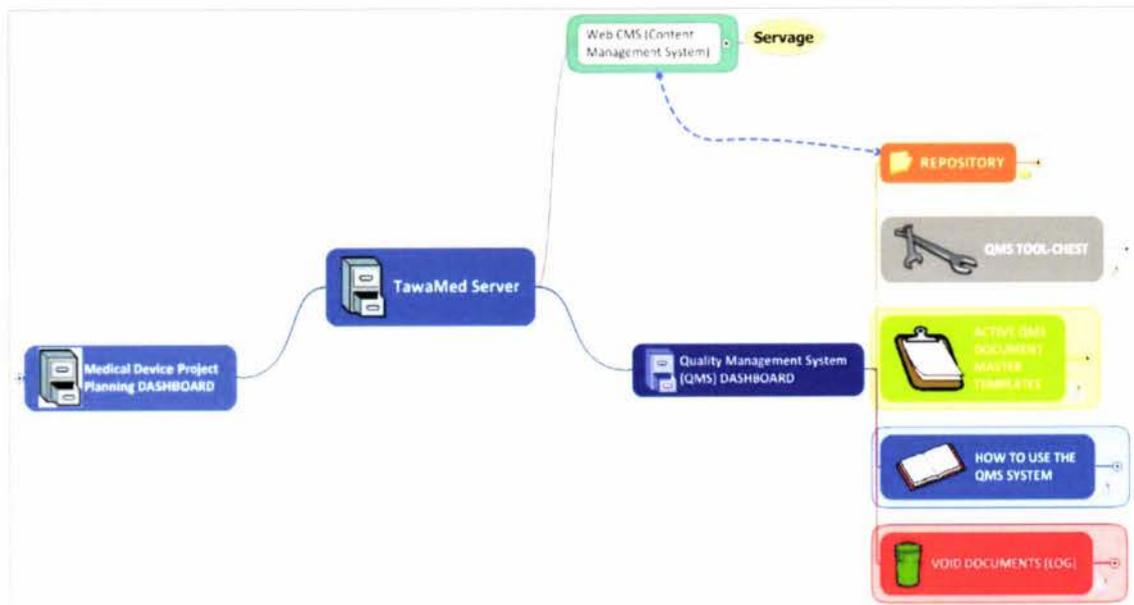


Figure 16 The Dashboard

The divisions of the Dashboard are as detailed below in Figure 17:

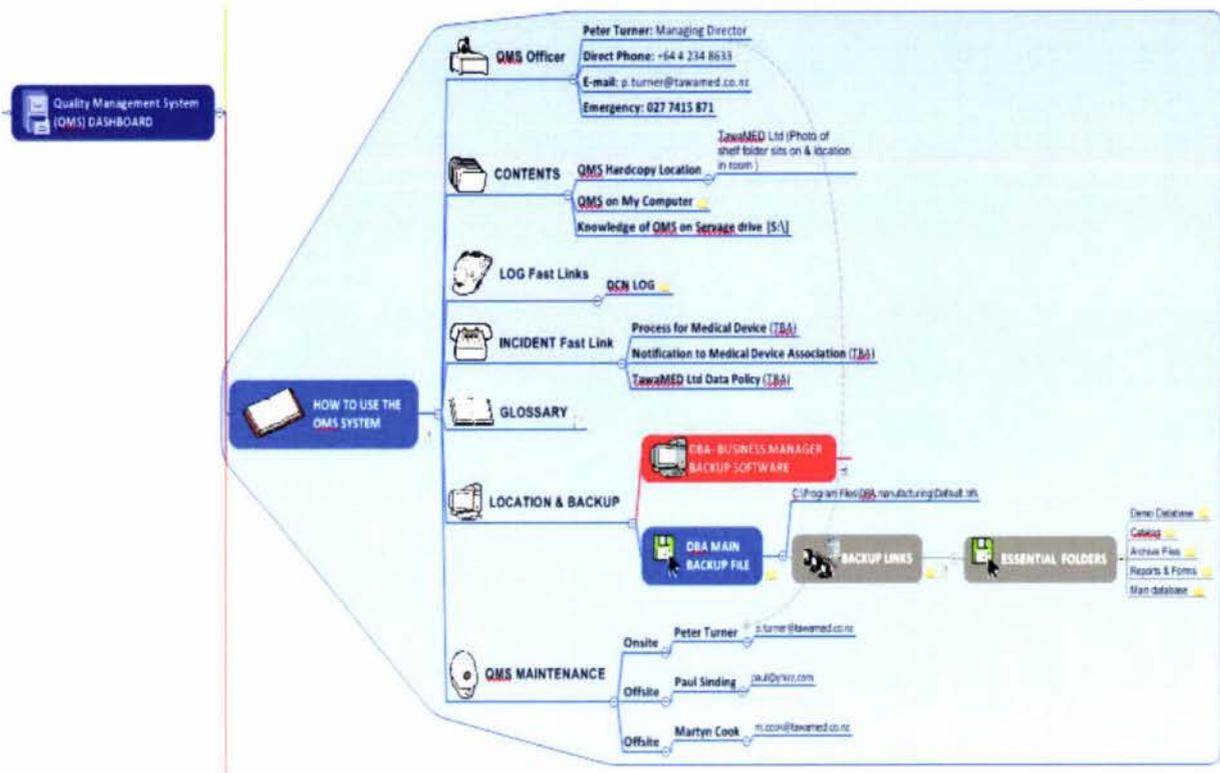


Figure 17. How to Use the Dashboard

Divisions of the Repository will be reflected in the Knowledge Library of the Servage Website, linked to the TawaMed QMS as shown in Figure 18.

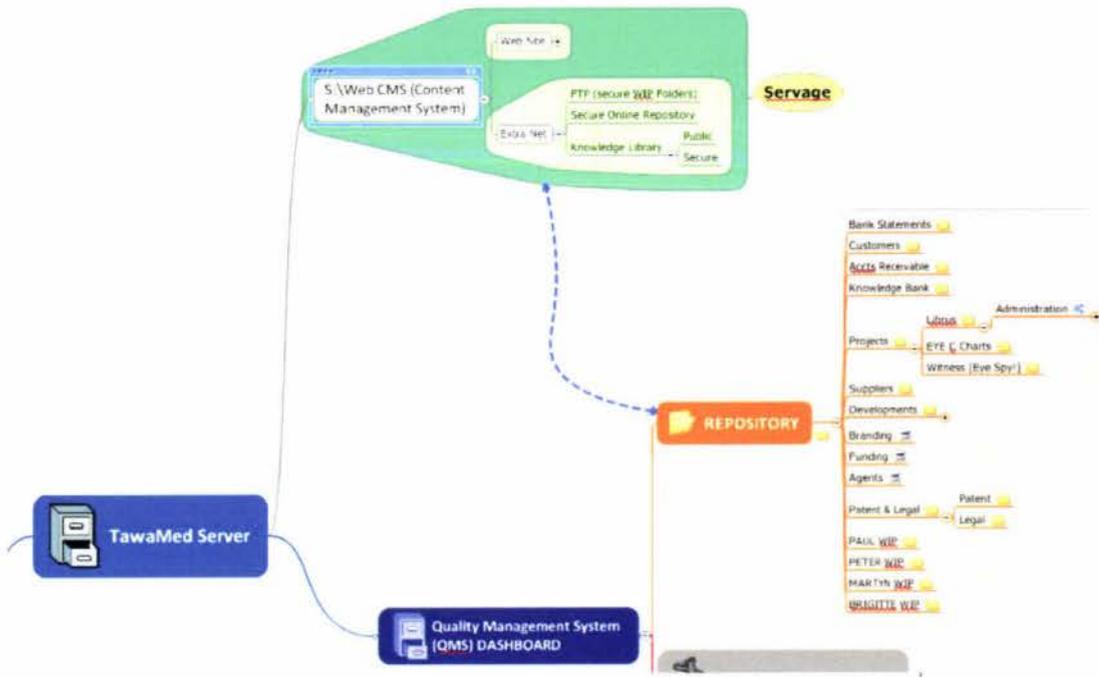


Figure 18. The Servage Dashboard

The QMS master templates expand from sub-titles and all active documents are hyper-linked as follows in Figure 19:

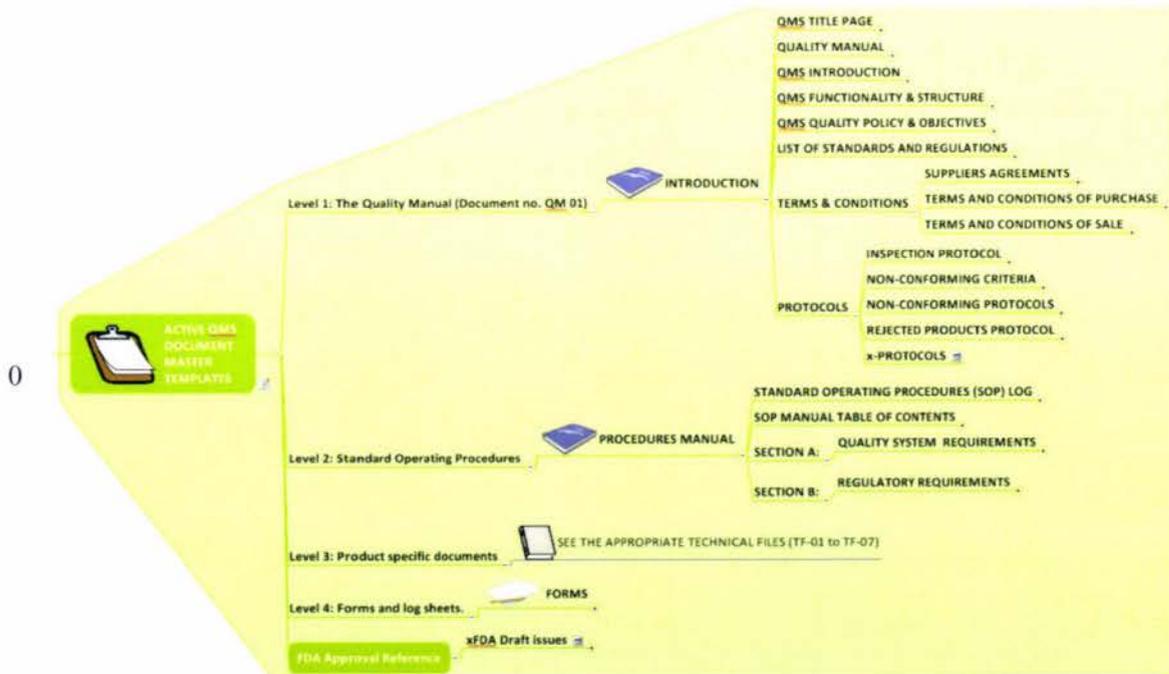


Figure 19. QMS Master Templates

Expanding at each node the Dashboard exposes all of the elements of the system and for project planning. Files in the QMS root directory of the TawaMed Server [Administrator] are available as attachments and hyper-links are available to other sites such as internet On-Line Help files. The Introduction includes the title pages, table of contents, functionality and structure. Standards, protocols and operating procedures are introduced. See also: Figure 14 Standard Operating Procedures Log; Figure 15 Forms (FRM) Log; & Sec 4.3.2.3 Level 3: Product Specific Documents.

4.4.1 The MD R&D Process

Expanding the Medical Device Planning Dashboard exposes the topics relating to the R&D process. See Figure 20.

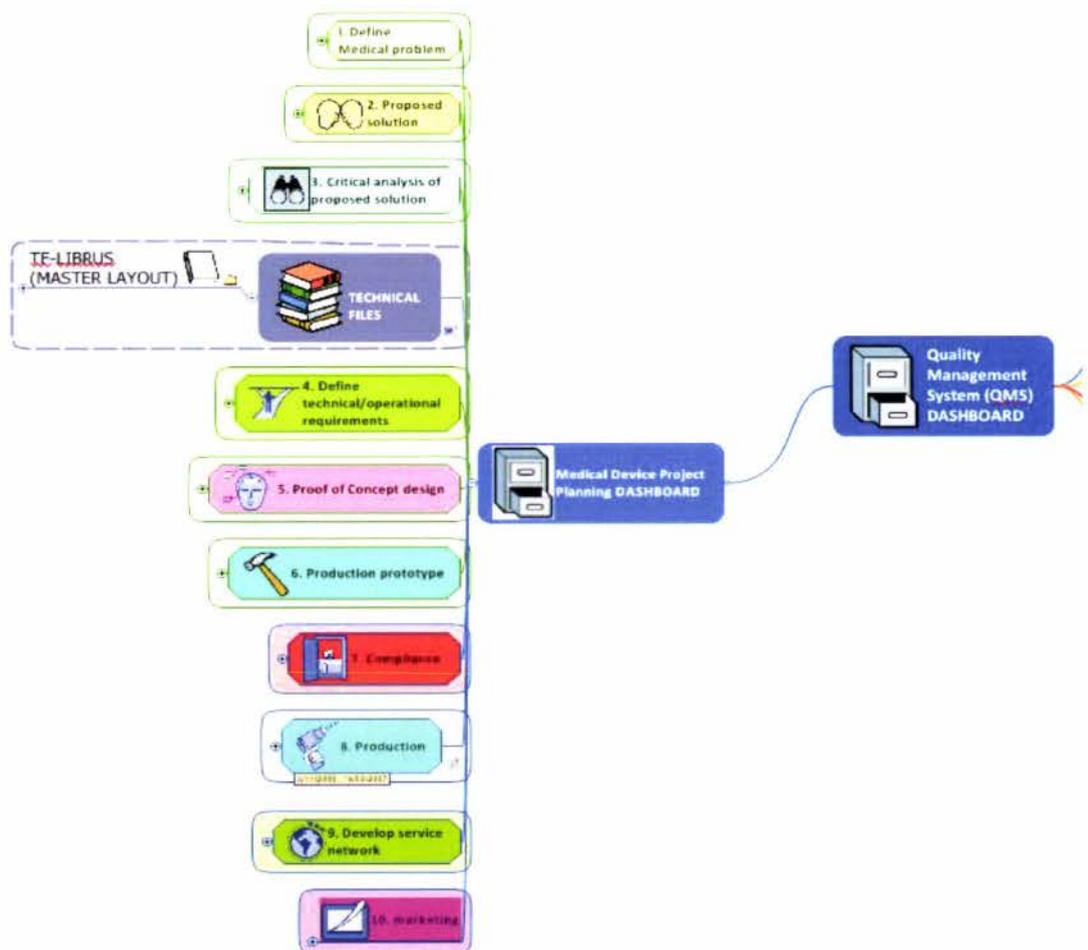


Figure 20. Medical Device Planning

The first three topics include Defining the Problem, Proposed Solutions, and a Critical Analysis of the proposed solution. See Figure 21.

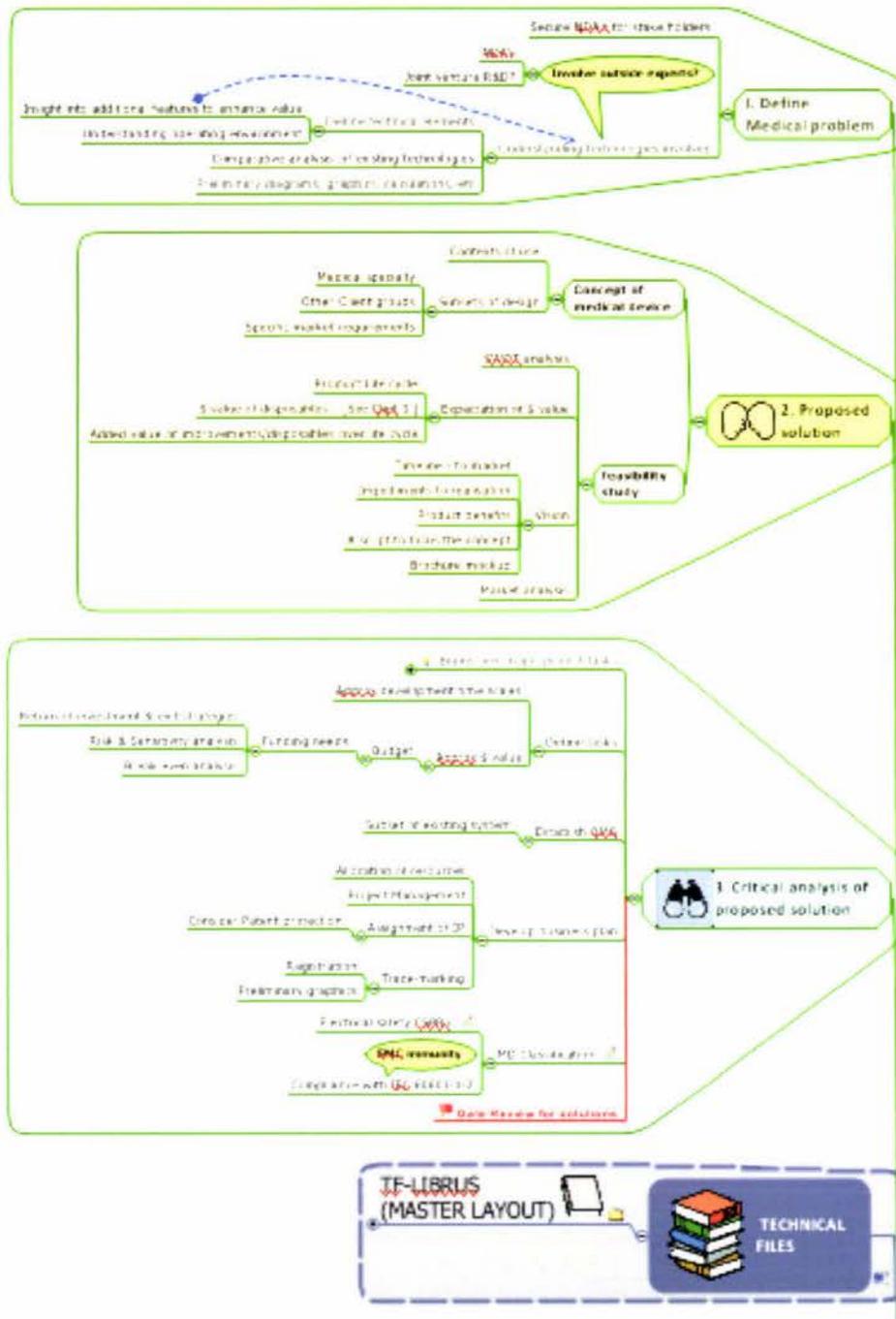


Figure 21. Medical Device Design Topics + TF - Librus

The Technical File [TF] attachments and hyperlinks relate to files or folders in different sections of the QMS including the Repository, TawaMed QMS, WIP folders, DBA spreadsheets, and QMS – TF. The TF is created at an early stage in the process to record the development at every level, assessing risk at each step

and striving to make prudent decisions to support the intended outcome. The development of the TF is dealt with more completely in Chpt 5.12.

The Medical Device design process continues by defining the technical/operational requirements, leading to a proof of concept design. See Figure 22.

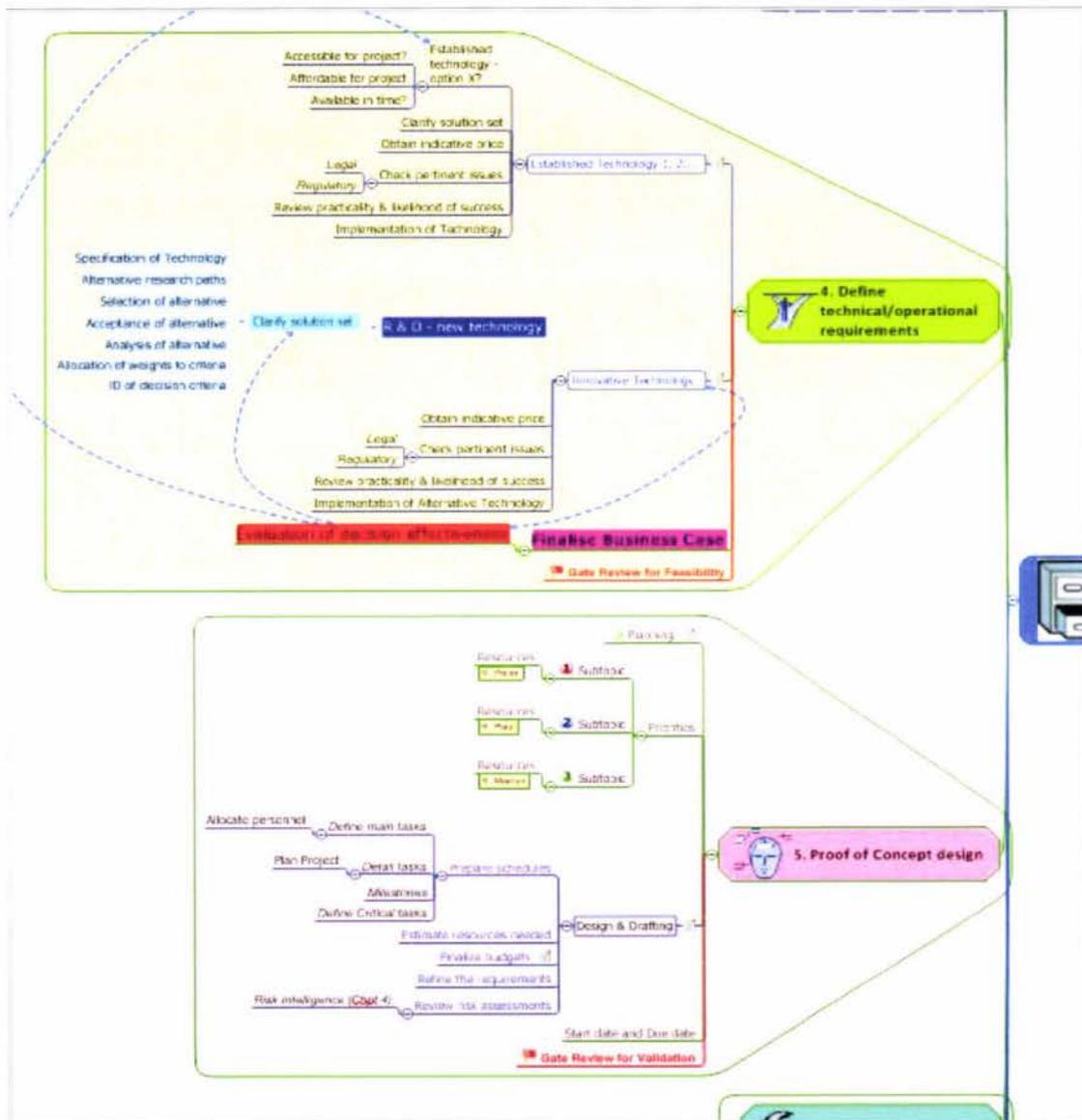


Figure 22. Technical, Operational requirements & Proof of Concept.

Moving into the production phase will allow the instruction and service manual documentation to be finalised. The servicing policy should be established and inventory levels and training of service agents planned. The marketing strategy will have been largely developed at this stage but will be moved forward with finalising the website, brochures and publicity material. See Figure 24.

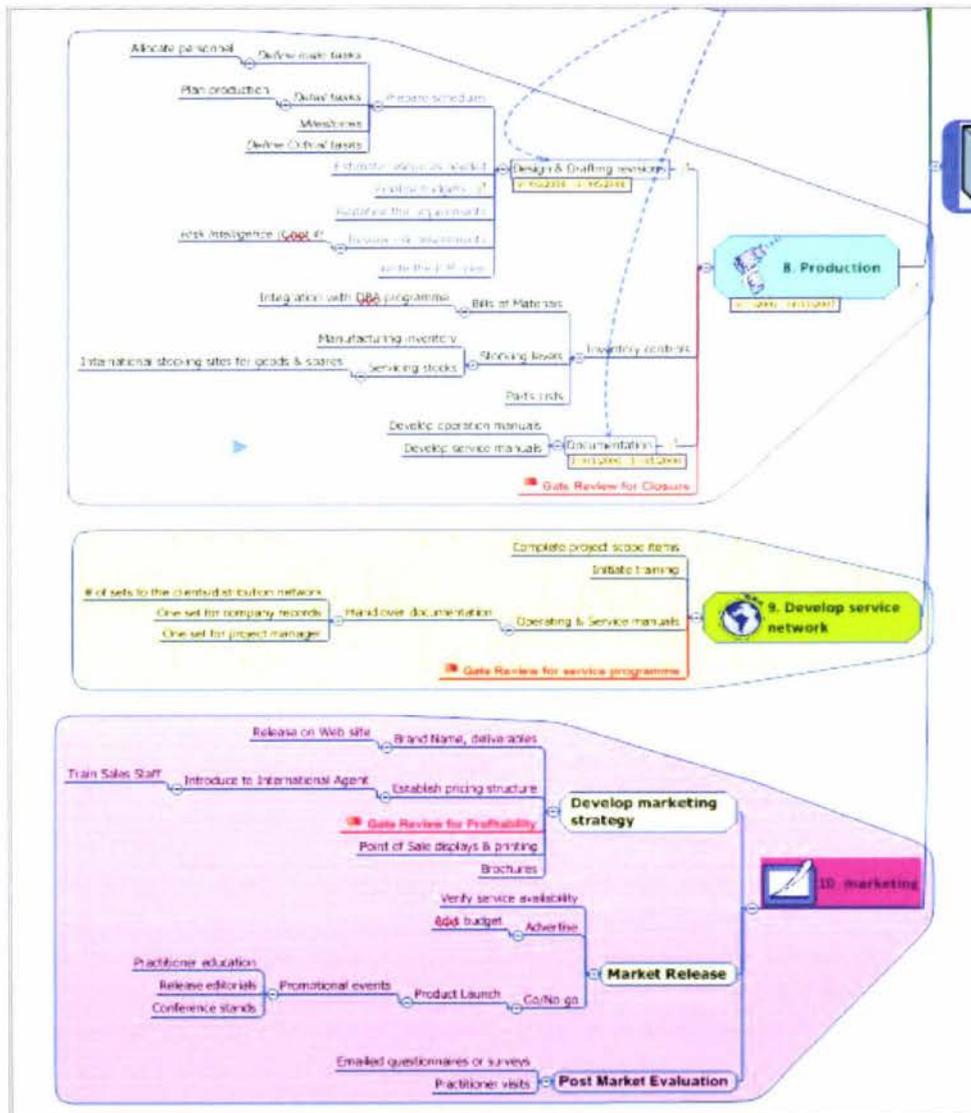


Figure 24. Production, Service and Marketing

4.5 Managing Risk

4.5.1 Process & Systems Standards - EMC & Electrical Safety

The IEC System for Conformity Testing to Standards for Safety of Electrical Equipment (referred to as the IECEE) is based on the use of specific IEC standards for electrical equipment. The CB Scheme is applicable to

electrical equipment within the scope of IEC standards for safety, accepted for use in the IECEE. The Scheme becomes operative for such standards as soon as at least three Member Bodies of the CMC, or the National Certification Bodies (NCBs) which they represent, have declared their recognition of CB Test Certificates. ^{94,95}

4.5.2 The CISPR11 Scheme

There are a range of standards that apply to the so-called CISPR11 scheme.

4.5.2.1 IEC60601-1

The IEC60601-1 standard; Medical Electrical Equipment – Part 1: General Requirements for safety is the cornerstone document addressing many of the risks associated with Medical Equipment. See Appendix 5 – IEC 60601-X Standards.

4.5.2.2 ISO 11137:1995; ISO 11135

ISO 11137:1995; ISO 11135 Medical devices – Validation and routine control of ethylene oxide sterilization. As so many MD's, especially those in contact with or implanted within the human body, require to be sterile, there are process standards including those for sterilization of devices by radiation, ethylene oxide, and steam. Standards also specify how statistical sampling is done. Still other standards specify safety requirements for specific medical devices and for validation and routine control.

4.5.2.3 UL/IEC61010

UL/IEC61010 vs UL508C: Safety requirements for electrical equipment for measurement, control and laboratory use.

4.5.2.4 AS/NZS/IEC 60950-1

AS/NZS/IEC 60950-1: Safety of information technology equipment including electrical business equipment. Current standards internationally refer particularly to IEC 60950. ^K

Companies typically demonstrate compliance with process standards during quality-system inspections or while registering new products. Specialist firms ensure conformance to safety standards by testing and certification to the specifications detailed.

^K See also: [IEC 60950](#), [UL 60950](#), [CSA C22.2 #60950](#), [EN 60950](#), [AS/NZS 60950](#), [NOM-019](#), [NB 1215](#)

4.5.3 Packaging

4.5.3.1 Treating packaging as an accessory

What makes packaging doubly important is that regulatory authorities recognize the critical nature of sterile barrier or a primary package by considering them components or accessories to the medical device. This implies that packaging is almost as important as the device itself. And it is. If a package does not keep for instance, a pacemaker sterile, patients will be put at risk. ⁹⁶

4.5.3.2 Standards for Packaging

ISO 11607: Packaging for terminally sterilised medical devices. Most single-use, sterilized medical devices can be opened with a high degree of confidence that it has remained sterile throughout storage, handling, and transportation.

4.5.3.3 Accelerated Aging

Accelerated aging is usually performed on packaged medical devices to document expiration dates.

4.5.3.4 Integrity During Transport

The most common defect in medical packaging is loss of sterile integrity from fractured thermoforms along with pinholes, slits, cuts, and tears in pouch packages. These defects come from handling (or mishandling), vibrations during transportation, storage, and impacts caused by dropping.

4.6 Practical Application of QMS

The application of a QMS to a MD development will be illustrated in Chapter 5. Case Study.

5 Case Study

5.1 Introduction

The following Case Study illustrates the implementation of a QMS applied to the design and manufacture of a MD. It describes the development of an illuminated bookstand, manufactured in two versions, together with a floor stand to support the assistive device version, for persons with a physical infirmity.

As this thesis investigates MD development, comparing the process with traditional development methodologies, this case study will highlight the issues that challenge the developer of MD's rather than discuss business planning in conventional terms.

Chapter 4, Figure 19, provides a framework to discuss the broad principles of the development process. The topic headings selected for discussion will focus on features of the development process that distinguishes a medical device from a domestic product.

5.2 Define the Medical Process - Understand the Operating Environment

5.2.1 Low Vision

The motivation to develop these MD's came about because of the long term involvement of the author as a Low Vision [LV] Clinician [a specialty of Optometry].^L

The majority of LV patients are elderly and suffer from a number of ailments; frequently muscle weakness, tremor and cognitive problems, e.g. memory loss, dementia or symptoms of a CVA. To overcome the handicap of LV, high magnification or very high levels of illumination may be used to enhance the visibility of print. High magnification may be achieved by using larger print, focussing at a closer working distance than normal [normal being generally in the range of 40 - 50cm], the use of optical magnification - magnifying glasses and telescopes, or electronic magnification or enhancement.

The elderly have difficulty maintaining print at a precise focal point and print is difficult to illuminate at a close range, especially if a hand held magnifying glass is interposed between the print and the eye. The positioning of a light source is critical for a variety of reasons

- to prevent shadows from the magnifier or reflections from it's front surface;

L Low Vision. Generally accepted def: Visual Acuity of less than 6/12 in the better eye; significant restriction of the visual fields, or any other visually disabling condition that causes a visual handicap.

- to prevent direct glare reaching the eyes from the source or indirect glare [reflected] from the page; and
- to utilise the maximum amount of light by positioning the source as close as possible [the square law affects luminance] and not too obliquely to the surface [the cosine law defines the vector normal to the surface].

The normal aging eye may require up to 10 times [X] the amount of light of a 10yr old to see with comparable visual performance, due to the loss of transmission in the optical media and neurological/physiological function. This is a property of aging that may be further degraded by the development of cataract and other pathologies such as glaucoma or age related maculopathy.

For a LV patient, very high levels, up to 30X [X = times] or 40X normal ambience - say 30,000 to 40,000 lux may result in significantly enhanced visual performance, frequently enhanced enough to not require image magnification. However it is uneconomical and highly inefficient to increase ambient^M light to provide high levels of task^N illumination. Combining a high intensity, glare free light source with a reading stand to restrain the position of the print for optimum visibility, is an attractive proposition.

5.2.2 Colour Vision Testing

Ophthalmic practitioners perform colour vision tests such as the Ishihara pseudo-iso-chromatic [confetti test], Lanthony D15 and 100 hue tests that require a source of illumination that has a correlated colour temperature of 5000K [K= °Kelvin]. They generally work in internal, artificially illuminated rooms. Unless special lamps are selected to illuminate the task, Colour Rendering by the ambient lighting may be substandard. It takes time to conduct the tests out in the light of a window away from the consulting room, so the practitioner may compromise the results of these tests by using room lighting.

A functional and convenient clinical solution for the practitioner would be to conduct colour vision tests using a bookstand, illuminated by a source with a high General Colour Rendering Index [Ra]^O

5.2.3 Colour Matching

Other colour critical matching tasks in industry and commerce may be enhanced using the Librus 300. Applications in the graphic, fabric, paint and printing industries will be assessed for markets potential.

M 'Ambient' is general illumination

N Task illumination pertains to the light directed at the task in hand and may be directed and being close, relatively low wattage.

O The General Colour Rendering Index, R_a, of a source has a maximum value of 100, which occurs when the spectral distributions of the test source and the reference source are identical.

5.2.4 Additional features to enhance value

- Other mountings may evolve in response to the demand from practitioners to mount the Librus 300 from their ophthalmic instrument stand.
- As the Librus 600 is designed specifically as an assistive device for the Low Vision user viewing print with a magnifying appliance, a floor stand will assist the maintenance of the correct working distance while seated.
- A dimmable version with a simplified floor stand may be attractive for musicians.
- There may be a modest demand for a bracket to project the bookstand forward from the piano to within the working distance.

5.2.5 Comparative Analysis of Existing Technologies

Extensive experience in the field of Low Vision with exposure to a broad range of LV products, and Internet searches, suggests that no other illuminated bookstand is currently manufactured, leaving this market niche available.

5.3 Preliminary Diagrams, Graphics, and Calculations

Uniformity of luminance over the whole of the bookstand area is desirable to maintain consistent visibility. Extensive ray tracing analysis was carried out to optimise the design of the reflector system to augment the direct radiation of the lamp which is greatest at the bottom of the stand. The representative diagram excludes layers that would have rendered the diagram incomprehensible! See Figure 25 below.

The goal was to disproportionately add light to the bottom of the stand and even the illuminance between the top and bottom. Radiance calculations would have been simpler if the source was a point rather than a tube with the large radiant area of a T8 fluorescent; the comparatively large diameter of the lamp compromises the efficiency of the reflector. However the luminance of the task is not the dominant feature with this device, rather it is the exceptional Colour Rendering capability [Ra = 98. See Footnote O, previous page.] that is important.

The Librus 600 on the other hand uses a 16mm diameter, high intensity lamp allowing better control of the reflected illumination. The deep reflector, illustrated in Figure 25, captures about 38% of the available reflected light.

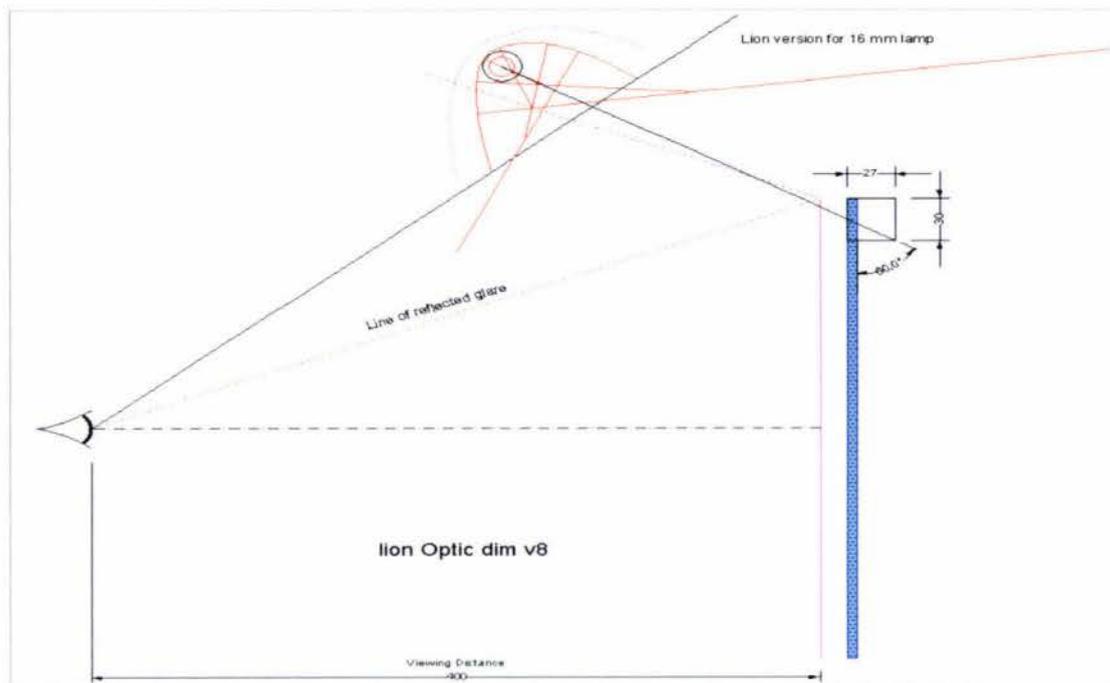


Figure 25. Preliminary calculation of the lamp position and reflector design

A viewing distance of 40cm has been selected for the calculations to be consistent with the industry standard for unity magnification. Instructions to the user about adjusting the Librus for optimum performance will include advice angling the stand so that when seated comfortably and wearing their reading spectacles or using a low vision appliance, they can view the centre of the page normal to the surface. In this position their sight line should just graze the outer margin of the reflector, no reflection should be apparent on a page of shiny paper, [the page should be below the 'Line of Reflected Glare'], nor should the lamp or surface of the reflector be visible.

5.4 Proposed Solution

5.4.1 Contexts of Use

The Librus 600 may be used in different contexts by a person handicapped with LV. For example in the kitchen the user may be reading for example, a cookery book, a telephone book or an appliance operating manual. Referring periodically to printed material infers functionality and convenience rather than comfort. The user may be standing, rather than sitting so the support or mounting for the Librus will be different to that used at the table writing a letter, or when seated reading in a comfortable chair by the fire.

Surveys of the experience of users will undoubtedly influence future design improvements of mountings.

5.4.2 Subsets of Design

For reading, the Model 600 will be supported in the optimum position (see above) by a stay angled away from the rear. The stay may be closed to allow the book-rest to be laid on a surface to become a writing platform. Removing the book rest ledge will provide an unimpeded surface. The horizontal surface of the Model 300 version will also be available to conduct colour vision tests that use coloured counters, sorted into an ordered colour sequence.

For the elderly person who may be bed-bound or reading in the comfort of a chair by the fire, a floor mount will support the Librus 600 in an optimum position while in a seat or reclining in bed.

5.4.3 The Design Philosophy

The philosophy behind the developments is illustrated in Figure 26 - Librus 300 & Figure 27 - Librus 600 below.

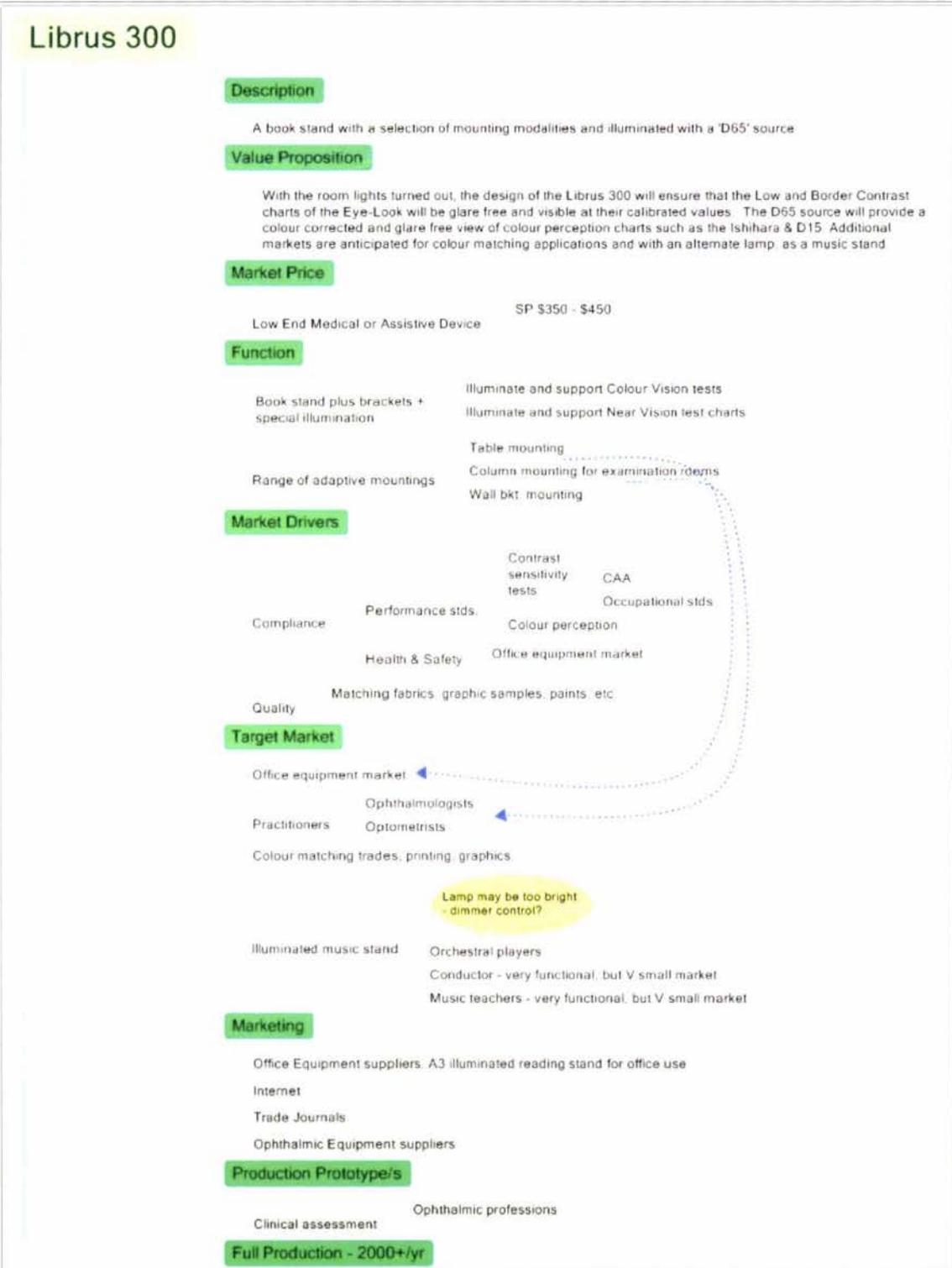


Figure 26. Librus 300 – Schema for Development

Librus 600

Description

A book stand with a selection of mounting modalities and illuminated with a high intensity tubular fluorescent lamp.

Value Proposition

The design will adapt as a book stand/writing tablet, uniformly illuminated over the entire surface with glare-free, high intensity illumination. Supporting print at a prescribed working distance, persons with LV are less fatigued, able to read comfortably for much longer periods and be less dependant on magnification aids.

Market Price

Low End Medical Device SP \$350 - \$450

Function

illuminate and support reading and writing material

Book stand plus brackets + special illumination

Table mounting

Range of adaptive mountings Floor stand for chair or bed side use

Market Drivers

| | | |
|---|-----------------|--|
| | Health & Safety | Telephone book Medication labels, sugar tests, syringe scales |
| Aging population & Pathologically induced LV, e.g. diabetes | Independence | Reading mail Writing letters Instructions, recipes, etc |
| | Recreation | Reading material |

Target Market

Low Vision - mainly elderly, but also increasing diabetic population

Marketing

Low Vision Clinics

Internet

RNZFB

Low Vision and assistive device suppliers

Interest group newsletters, e.g. Grey Power

Production Prototype/s

Clinical assessment Low Vision Clinics

Full Production - 4000+/yr

Figure 27. Librus 600 – Schema for Development

5.4.4 Design Summary

To summarise, the Model 300 & 600 use the properties of a common bookstand, but each model has a specific luminaire. The Model 300 utilises a shorter, larger diameter, colour corrected fluorescent source for colour vision testing. The brightness of the task will be appropriate for such tests.

The function of the Model 600 is on the other hand to provide a high intensity, even, glare free luminance on a reading/writing bookstand, to optimise the visual efficiency of people with Low Vision.

5.5 Product Life Cycle

The Librus products have an indefinite life cycle; there are no parts to wear out, apart from the gradual degradation of the fluorescent lamp, expected to last approx. 4,500 hrs.

However the European Commission (EC) issued Directives 2002/96/EC on the 27th Jan 2003 with the goal of dramatically cutting down on the accumulation of toxic materials in municipal waste.^{97,98} See Appendix 2.

There are two parts. The Restriction of Hazardous Substances (RoHS) Directive and the Waste Electrical and Electronic Equipment [WEEE] Directive.⁹⁷ WEEE describes what should be done with waste equipment; RoHS describes what substances must be excluded from the manufacture of devices and is discussed below in Cl. 5.5.1.

A large part of the legislation focuses on eliminating the use of lead, in particular, the use of lead-bearing solder, in electrical and electronic equipment.

If eliminating lead on PCBs was easy to do and raised no reliability concerns, there would be no reason for concern. As responsible members of the community, manufacturers would convert to lead-free assembly of PCB's right away, but the conversion itself is not completely straightforward.⁹⁹ Considerable heat stress is induced in components soldered with high temperature melting point, lead free alloys and the challenge is for manufacturers to develop component housings that protect the temperature sensitive elements from the heat conducted from the solder terminals and improved soldering technology.

5.5.1 Restriction of Hazardous Substances [RoHS]

Article 4 of the RoHS Directive requires that as of July 1, 2006, new electrical and electronic equipment entering the market must not contain the following materials:

- Lead
- Mercury
- Cadmium
- Hexavalent chromium
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ethers (PBDE)

Mercury is present in small quantities within the Osram tubular fluorescent lamps used in the Librus products. They have stated in Figure 28 their policy regarding hazardous materials.¹⁰⁰

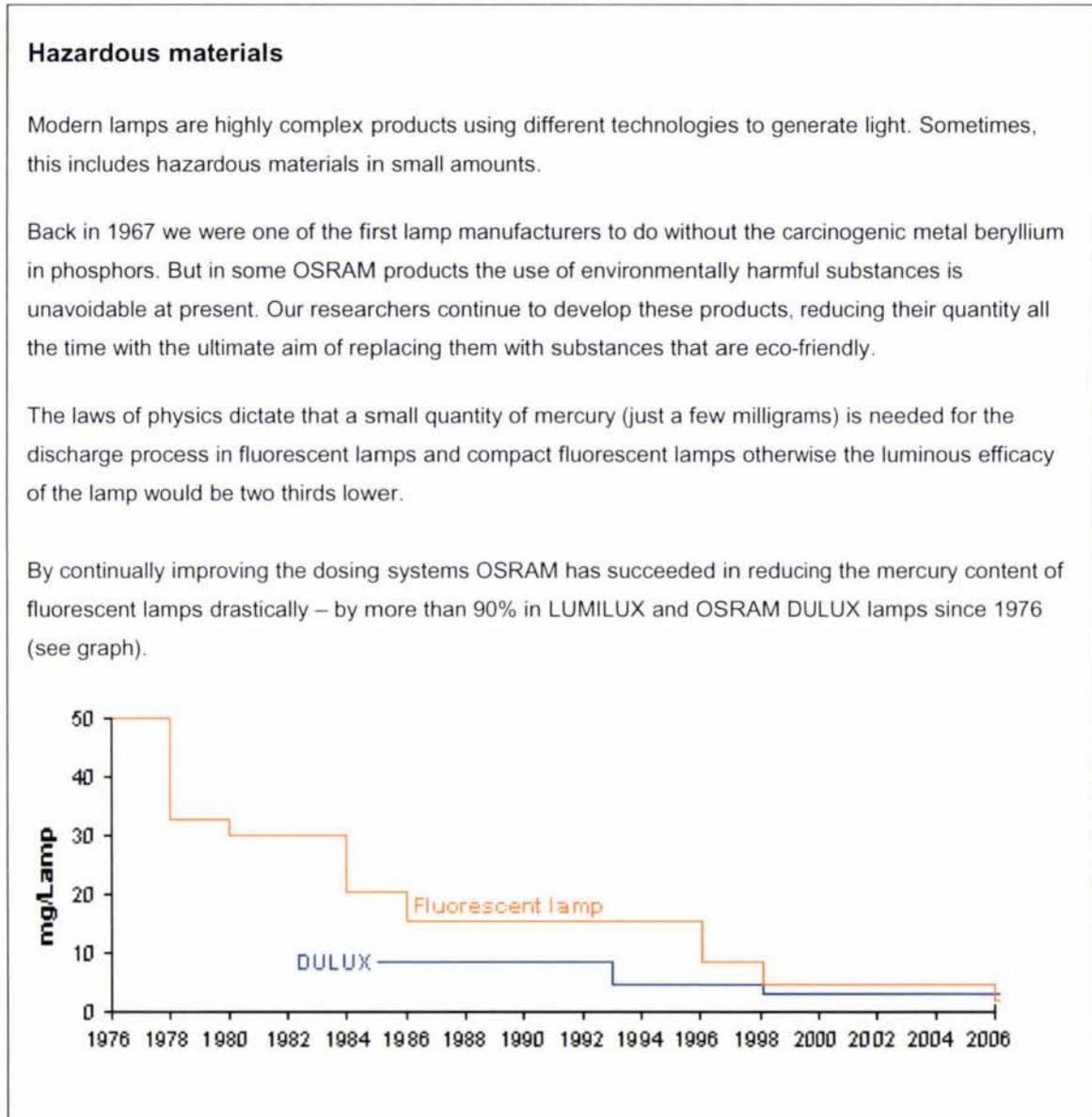


Figure 28. Osram Policy on Hazardous Substances

Mercury, which might be used in relays, could also cause problems on PCBs. The use of PBB and PBDE has been restricted for several years.⁹⁹ Hexavalent chromium and cadmium are seldom used in

electronic systems.

The electrical components for the Librus, including the lamp and holders, cable set, IEC combination [cable] inlet plus switch & electronic ballast will be purchased from accredited suppliers who will have already conformed to the standards required for a CE mark. Their documentation together with that created by the TawaMed QMS will provide an audit trail to ensure that complete system is compliant.

The wiring harness connections will be crimped into terminals, lugs, or inserted into insulation displacement terminals. No soldered connections will be necessary, however the electronic ballast will include a PCB that has soldered connections.

The manufacturer of the electronic ballast will be bound by the directive, but not as a medical device currently exempted from the RoHS Directive requirements. However Article 2 (Scope) of the RoHS directive states the following:

- 1. Without prejudice to Article 6, this Directive shall apply to electrical and electronic equipment falling under the categories 1, 2, 3, 4, 5, 6, 7, and 10 set out in Annex IA to Directive No 2002/96/EC (WEEE) and to electric light bulbs, and luminaires in households.*

It is unclear whether any action is pending at the EC that would cause the exemption of medical devices to be removed or even be reexamined. It is always difficult to prove that no action is pending within a regulatory body, but to date nothing has surfaced. All signs seem to show that the medical device exemption will remain in the directive for the foreseeable future. It is very clear that the 2006 deadline is not applicable for medical devices now and there has been no move yet to make them subject to the RoHS directive.⁹⁸

The bonus of keeping the status quo is that the medical device industry has some time to prepare. Device manufacturers can use the time to monitor the progress made by other industries and learn from their mistakes and successes. However medical devices can and arguably should, be made lead-free.⁹⁸

It is significant that large manufacturers are taking their corporate responsibility regarding RoHS very seriously and have issued directives to their design and development departments about banned substances. An example is the company directive - 'The Ericsson lists of banned and restricted substances.'¹⁰¹

5.5.2 Waste Electrical and Electronic Equipment [WEEE]

As the volumes of the Librus product to be recycled onto the EU market are likely to be modest and the recycling obligations will extend into the future, the most efficient compliance vehicle will be to subscribe to a recycling agency such as the European Recycling Platform.¹⁰²

There are a number of competitive organisations in Europe. For one organisation there is a joining fee of €10,000 in first year which allows for less than 1000 tonnes of waste [the lowest category] to be processed. Thereafter there is an annual fee of €8,000. As an example, the box details the recovery fee with indicative charges for Great Britain.

Compliance

ERP, as a not-for-profit organisation, is committed to providing a competitive service at the highest level and for the best price. Compliance costs differ depending on the category of products you supply and whether you supply business/non-household or household products. ERP offers a single price per category (£ per tonne for collected & treated). Members of ERP UK will pay on the basis of what is actually recycled, not what they put on the market.

ERP is committed to producing continuous cost and quality improvements in the WEEE compliance system. Our pricing policy is adaptable to this changing environment. For information on our current prices for B2C and B2B compliance, email uk@erp-recycling.org

B2B reporting will cost £1,500 per year

Membership

ERP UK annual membership rates vary according to the weight of products placed on the market annually.

Standard: £3,000 for Year 1 (£1,500 for subsequent years)

SMEs (<15 tonnes per annum): £1,500 per year (there are no additional compliance costs if this 15 tonnes does not include cold display technologies and lamps).

We offer a reduced annual membership rate for companies operating both in the UK and Ireland of £2,650 for the UK and €500 for Ireland. And for joint (B2C and B2B) members, we waive the B2B reporting fee.

Clearly these compliance costs have to be factored into the selling price of the product and as this requirement is not mandatory in NZ or Australia, it will be logical to initially build the local markets. When the sales potential justifies entering the EU markets, it will be appropriate to join a recycling scheme.

5.6 Risk Analysis - Electrical Safety and Electromagnetic Compatibility [EMC]

5.6.1 Introduction

The electrical safety of the Librus must be certified by laboratory accredited to EN ISO14971:2007. This certification is part of the Risk Analysis process of the QMS.

All electrical products, whether MD's or consumer, are bound by NZ regulations concerning Electrical Safety and Electromagnetic Compatibility [EMC]. Compliance for both regimes is enforced by the Ministry of Economic Development, with Electrical and Electronic products safety administered by the Energy Safety Division and the EMC regulations by Radio Spectrum Management Division.

5.6.2 Electrical and Electronic Equipment Safety – Overview ¹⁰³

5.6.2.1 Overview

From the Overview it is apparent that Librus products are regulated by the clauses highlighted in yellow below.

'New Zealand's Electrical and Electronic products safety Regulatory Regime is a performance based regime, utilising internationally aligned Standards. It is implemented through a single economic market philosophy with Australia, and incorporates a number of Mutual Recognition Agreements [MRAs] with NZ's trading partners.

The regime is risk management based and applies three levels of Regulatory intervention:

- *Essential Safety – with a range of recognised Standards – low risk products,*
- *Supplier Declaration of Conformity (SdoC) - medium risk products,*
- *Approval (ISO type 1 certification) - high risk products.*

A voluntary Product marking system – The Regulatory Compliance Marking (RCM) – is available as part of the Safety Regime.

The regime applies to all electrical and electronic equipment sold, installed and used in New Zealand, including medical-electrical and hazardous area equipment - at all voltages.

The regime has a range of enforcement options and is administered by Energy Safety, a part of the Ministry of Economic Development.

General Essential Safety - Electrical Product Safety Obligations

All Electrical and Electronic Products sold in NZ are required to be safe. ^N

Products Requiring a Supplier Declaration of Conformity (SDoC)

^N An overriding standard AS/NZS.3820 "Essential safety requirements for low voltage equipment" mandated by Regulation 76(a) of the Electricity Regulations 1997 applies to the Librus products. ¹⁰⁴ However a list of 'Deemed to Comply' Standards also must be adhered to that relate to discrete components within the MD's. ¹⁰⁵

*Products considered to offer a medium (and high) safety risk are required to be covered by a Supplier Declaration of Conformity (SDoC) completed by the supplier of the product in New Zealand prior to sale. (High risk products also require **Approval** prior to being offered for sale.).....¹⁰⁴*

5.6.2.2 Products Requiring a Supplier Declaration of Conformity (SDoC)

'If you are a retailer or an installer and have been supplied with an electrical appliance from another New Zealand supplier the law requires that the equipment has a formally completed supplier declaration of compliance prior to legal sale in New Zealand.....'¹⁰⁶

Product Categories Requiring SDoC:

- [Household and similar appliances](#)
 - [Lighting Fittings](#)
 - [Wires and Cables](#)
 - [Power Supplies and Transformers](#)
 - [Switches, Connectors and](#)
- [Protective Devices](#)
 - [Electric Tools](#)
 - [Welding Equipment](#)
 - [Audio and Video Products](#)
 - [Information Technology Products](#)
 - [Transportable Tools](#)

Note: Some products requiring a [Supplier Declaration](#) also require [Approval](#) prior to sale.....

Lighting fittings are included in this latter category.

[Completing a Supplier Declaration of Conformity \(SDoC\)](#)

A Supplier Declaration of Conformity (SDoC) must be completed by the New Zealand... The supplier declaration is a statement by the NZ supplier that the product they... The Declaration must be made using the prescribed form "ESS1/02" [ESS1/02 is the form for 'Supplier Declaration of Compliance' – see below. The terms Compliance and Conformity appear to be used interchangeably] and must....¹⁰⁶ Basis of claimed safety (i.e. compliance with Regulation 69) by, or where appropriate... If none of the aforementioned evidence is available...

5.6.2.3 Compliance

Highlighted below are the categories that are subject to Electrical and Electronic product safety compliance

requirements for SDoC.

Note: Lighting fittings – are included with the Declared Articles as below.

'Information relating to the Electrical and Electronic product safety compliance requirements for SDoC and Declared Articles (Approval Requirements) are grouped in accordance with IEC product Standards groupings as below

- [Tool Portable Type](#)
- [Transportable Tools](#)
- [Household and similar appliances](#)
- [Lighting fittings](#)
- [Cables and wires](#)
- [Power supplies and transformers](#)
- [Switches connectors and Accessories](#)
- [Electric tools](#)
- [Welding equipment](#)
- [Audio and video products](#)
- [Information technology products'](#)

5.6.2.3.1 Lighting Fittings

The category of Light Fittings is further subdivided into the components highlighted below including the Fluorescent Lamp Ballast and are subjected to SdoC requirements:

'The following light fittings are subject to Approval and/or SDoC requirements.

Products subject to both SDoC and Approval are identified by an ++ indicator.

- [Luminaries portable type ++](#)
- [Decorative Lighting Outfits](#)
- [Fluorescent Lamp Starter](#)
- [Fluorescent Lamp Ballast](#)
- [Inspection Hand Lamps ++](#)
- [Light Fittings \(domestic and similar\)'](#)

5.6.2.3.2 Products Requiring Approval

'Products considered to offer a high safety risk are required to be approved, or covered by a recognised certification, (in addition to being required to be covered by an SDoC) prior to being offered for sale.'

5.6.3 Recognised Certification

NZ's Electrical equipment regime allows for the recognition of Approvals issued by foreign Regulators and Product Certification issued in accordance with NZ's MRAs.

This recognition implies that components of the MD's do not have to be resubmitted for certification if they already have a manufacturer's Certificate of Conformity.

Never-the-less completed MD's must be submitted to a Recognised Testing Laboratory for Electrical Safety Certification. The results are then submitted to Energy Safety for approval using Form ESS2/02. See Appendix 7.

5.6.4 Electromagnetic Compatibility [EMC]

5.6.4.1 Summary of Compliance Requirements

EMC and radio product compliance is based on the principle of supplier self-declaration. The supplier of a product must comply with the requirements of the level of conformity allocated to that product. These are summarised as follows:

Level 1 (low risk)

- Product must comply with an applicable standard.
- Supplier must hold a compliance folder containing a declaration of conformity and product description (Radio Product only).
- Product must be labelled (Radio Product only).

Level 2 (medium risk)

- Product must comply with an applicable standard.
- Supplier must hold a compliance folder containing a declaration of conformity and test report, or other reasonable evidence of product conformity. See Cl. 5.4.5.5 Compliance Folder.
- Product must be labelled. See Cl. 5.8 Labelling for Electrical Safety & EMC.

Level 3 (high risk)

-
- Product must comply with an applicable standard.
 - Supplier must hold a compliance folder containing a declaration of conformity and test report from an accredited test facility.
 - Product must be labelled.

The Librus MD's fall into the category of medium risk as they utilise an electronic ballast that could potentially be a source of radio interference.

The Level of Conformity for the Librus will be A2.

'Level of conformity A2: Where a product is in a class to which level of conformity A2 applies then, prior to supplying the product, the supplier must ensure that the product conforms to an applicable standard and:

- *must label the product with the supplier's supplier code number;*
- *must create a compliance folder containing:*
- *a declaration of conformity;*
- *a product description; and*
- *a test report, or manufacturers performance specifications, or other reasonable documented evidence of product conformity.'*⁹⁵

5.7 Labelling for Electrical Safety and EMC. ⁹⁵

Electrical safety requires a cautionary label adjacent to Power Inlet. ^O

See Figure 29.

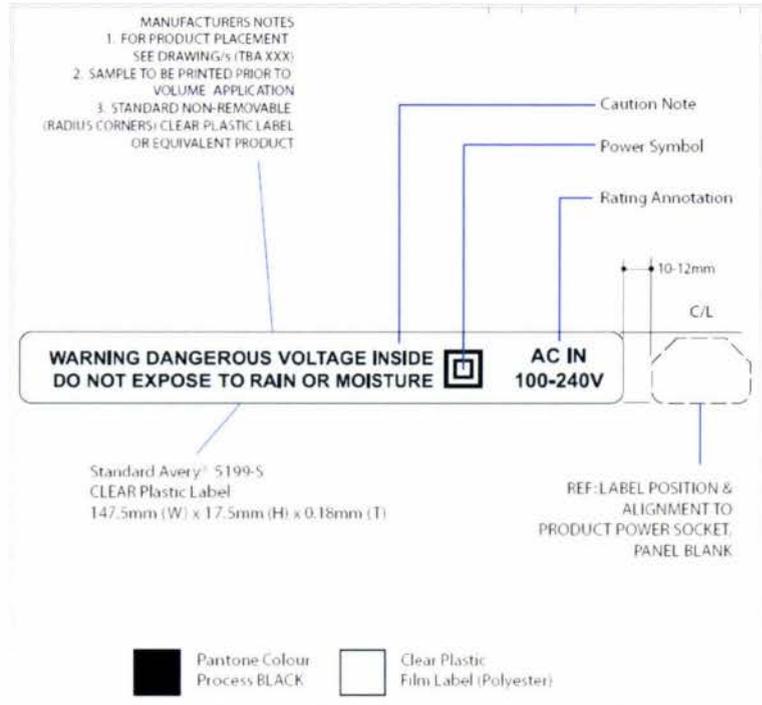


Figure 29 – Label Adjacent to the Power Socket

Over the entry panel to the electrical chassis a further cautionary label is required. See Figure 30

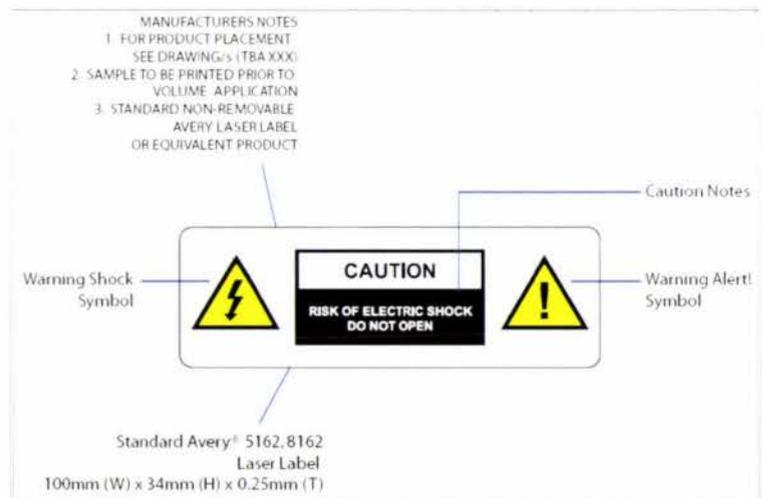


Figure 30. Label Adjacent to Cover

^O All labels designed by Paul Sinding – Design Consultant.

5.8 'The Label on any Product' ¹⁰⁸

- must be legibly and durably applied on the external surface of the product as near as is possible to the model identification. Where this is not possible due to the size or nature of the product, the label may be placed on the packaging or warranty or instructions for the product.
- may be reproduced in any colour provided that there is sufficient contrast with the background colour or relief.
- may also be placed on promotional material associated with the product.
- the compliance mark on any label must be no smaller than 3mm in diameter and the supplier identification characters must be no less than 1mm in height.
- if a supplier is labelling a product with the RCM compliance mark, the supplier must comply with the requirements of AS/NZS 4417.
- irrespective of the supplier identification used by a supplier, a supplier must not label a product unless the supplier has applied for and been allocated, a supplier code number.
- no variations are permitted to a compliance mark.
- if the labelling of a product in accordance with the requirements of this section is not possible, the supplier must obtain a written exemption from the Chief Executive before supplying the product.

The Product Label is shown in Figure 31.

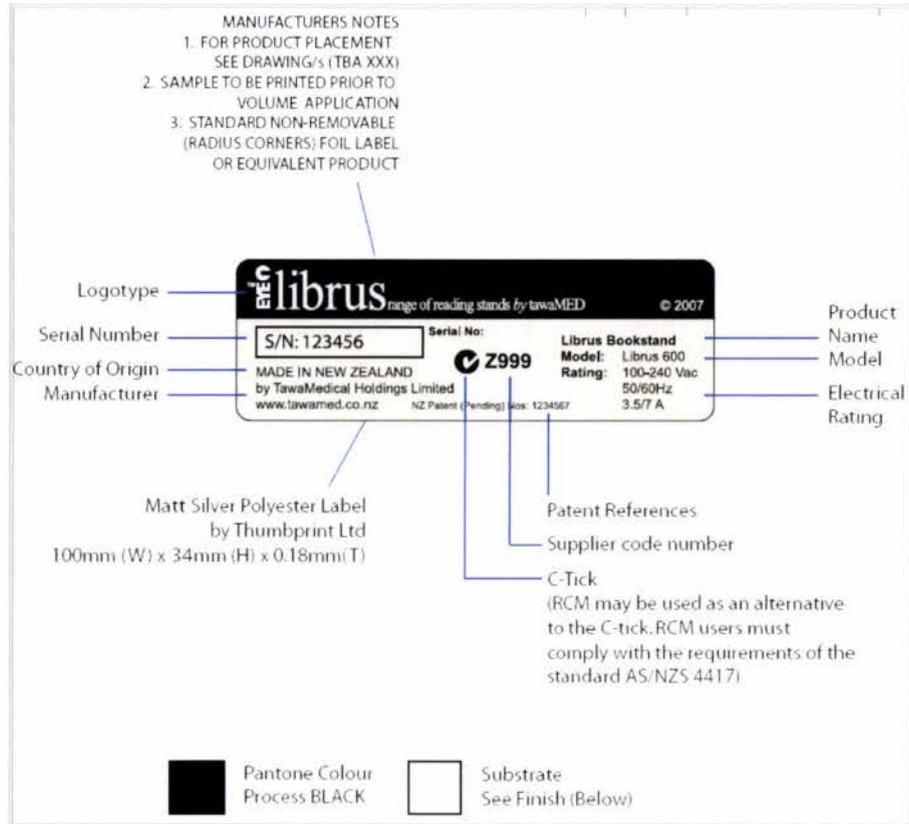


Figure 31. The Product Label

'In most instances the [label](#) will include the compliance mark (C-tick or RCM) and the [supplier code number](#) (SCN) thus:' ¹⁰⁷ See Figure 32.

Figure 32. C-tick



'If, however, the level of conformity allocated to a product is prefixed by the letter "A" (e.g. A1, A2 or A3) then the only label permitted is the supplier code number (SCN). The product must not be labelled with the compliance mark.' ¹⁰⁸

5.9 Compliance Folder ⁹⁵

The following is the statutory requirement for a compliance folder.

'A compliance folder consists of documents as prescribed in Section 4 of this notice. The compliance folder:

-
- *must be in English;*
 - *may be kept in an electronic form;*
 - *must, if only available in a written form, be held at the suppliers place of business in New Zealand;*
 - *must be retained by the supplier for a period of 5 years from the date on which the product ceases to be supplied by the supplier;*
 - *must, in regard to any variants of the product, contain a signed statement that the variations do not alter the electromagnetic compatibility or radio frequency emission characteristics of the product;*
 - *must, if a certificate issued by another administration is the basis for the declaration of conformity, include evidence that the product has been altered to comply with new Zealand requirements;*
 - *must, at the written request of the Chief Executive, be made available by the supplier in written form within 10 working days of the request being made; and*
 - *strict compliance with prescribed forms is not necessary and substantial compliance, or such compliance as the particular considerations of the case allow, is sufficient. [Quote – poor English?]*

Copies of the above documents will be kept as electronic copies in the TawaMed QMS/Compliance/EMC/Compliance folder with hard copies in the Librus Technical File.

In addition the following documents in the Table 1 will be administered in the specified locations.

| <i>Documents</i> | <i>Location</i> |
|---|---|
| Power ratings (products) | Librus TF |
| Drawing naming convention | TawaMed QMS. Librus TF |
| Serial number / batch numbers | Product Librus TF |
| Aust/NZ compliance + international? | QMS Repository – WIP, then TawaMed QMS & Librus TF |
| WIP (UL/CE/Other) (Tick mark) | QMS Repository – WIP, then TawaMed QMS & Librus TF |
| Suppliers Declaration (NZ) Registration >> (AUS) | QMS Repository – WIP, then TawaMed QMS & Librus TF |
| Testing for compliance (nominate a test lab / time-frame / cost) | QMS Repository – WIP, then TawaMed QMS, & Librus TF |
| Translation policy and language texts for manuals.(eg: more than one language >> typical for CE compliance and selling into Europe) | QMS Repository – WIP, then TawaMed QMS. |
| Policy for file retention (online/offline) | TawaMed QMS, & Librus TF |

Table 1. Document Management for Electrical Safety & EMC

5.10 Timeline - to Market

The initial line of development for the Librus utilised a twin skin ABS construction to provide a medium that could be sculptured for aesthetic appeal. After nearly nine months of work on the design to reduce the part count and simplify the assembly, the only company capable of this form of manufacture in N.Z. quoted in excess of \$55,000 for die-making and tooling, nearly double the original estimate. This investment might have been justified if there was an established market and the capital could be amortised over a short period, but when the direct and servicing of capital costs were factored into the selling price, it pushed it beyond what the market would probably tolerate. The twin skin vacuum formed construction was abandoned and alternate technologies investigated. It was resolved as a result of the experience, that the company would never again be beholden to only one supplier. To decrease the commercial risk and encourage competitive component pricing, a decision was made to use simpler CNC turret punched steel components, with the expectation that cost would be ultimately pulled out of the design by dedicated component dies. A revised,

basic time-line for the development is featured in Figure 33 below.

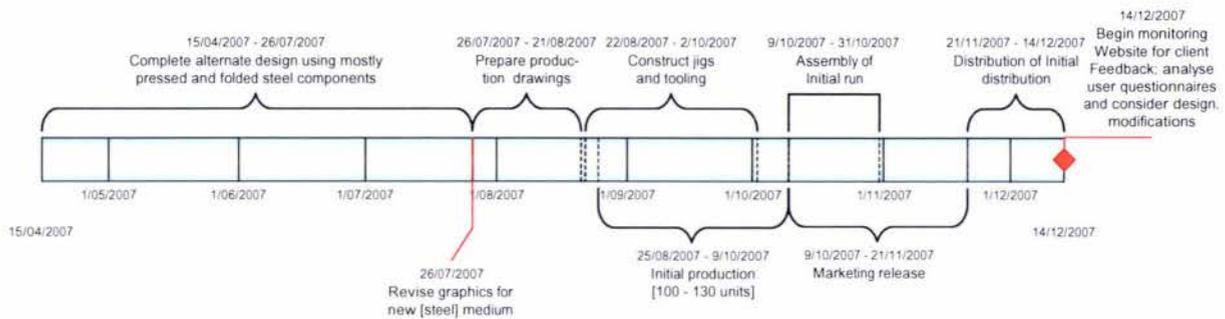


Figure 33. Revised Time-line; Librus Project

5.11 Intellectual Property

The principles of design incorporated into the Librus are not novel and therefore not considered patentable.

Never-the-less as previously noted there are no other similar devices marketed, certainly not in New Zealand or Australia. Elements of the design such as the reflector are carefully engineered, shaped to optimise the output of each of the fluorescent lamps. Maybe in time other manufacturers will produce a competitive product and the goal will be to find ways of reducing production cost or adding value to retain market share.

5.12 Identification

5.12.1 Trademarking and Branding

Trademarking and branding for the company is currently under development. The TawaMED brand will be synonymous with a range of MD's and assistive devices that will be released progressively. Initially the products pick up the concept of Eye – See, or C and in it's stylised form shown on the next page, it will be associated with the products in the LIBRUS range. See Figures 34 & 35.

5.12.2 CE Mark

The CE mark allows free marketing within the 28 countries of the European Economic Area (EEA) and Turkey. For NZ firms a strategy may be to pursue the CE certification while the product is in the approval process by the FDA. The CE certification can be often achieved prior to the FDA's approval, thus enabling the device to be sold in Europe and generating substantial revenues.¹²⁵

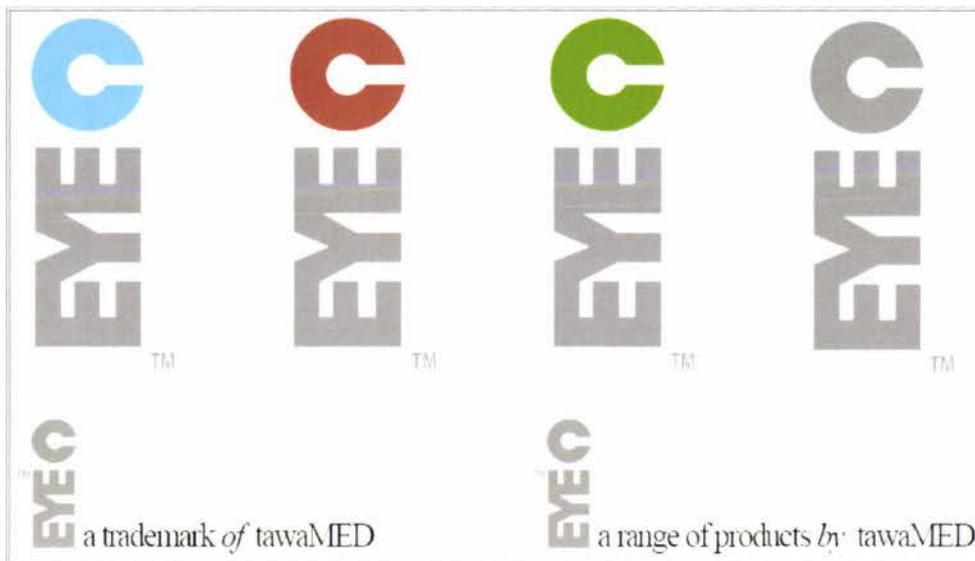


Figure 34. The Eye-C Brand

The possibility of trade-marking the product names of LIBRUS 300 & 600 is currently being investigated and they will define the current products under the Eye C brand. See Figures 34 and 35.

Word associations with Eye provide attractive possibilities as product names and it is likely that the theme will be continued with this trademark ultimately denoting a number of visually related Medical or Assistive Devices. Possibilities include Eye – Adapt , Eye-Look, Eye – Seek, etc.

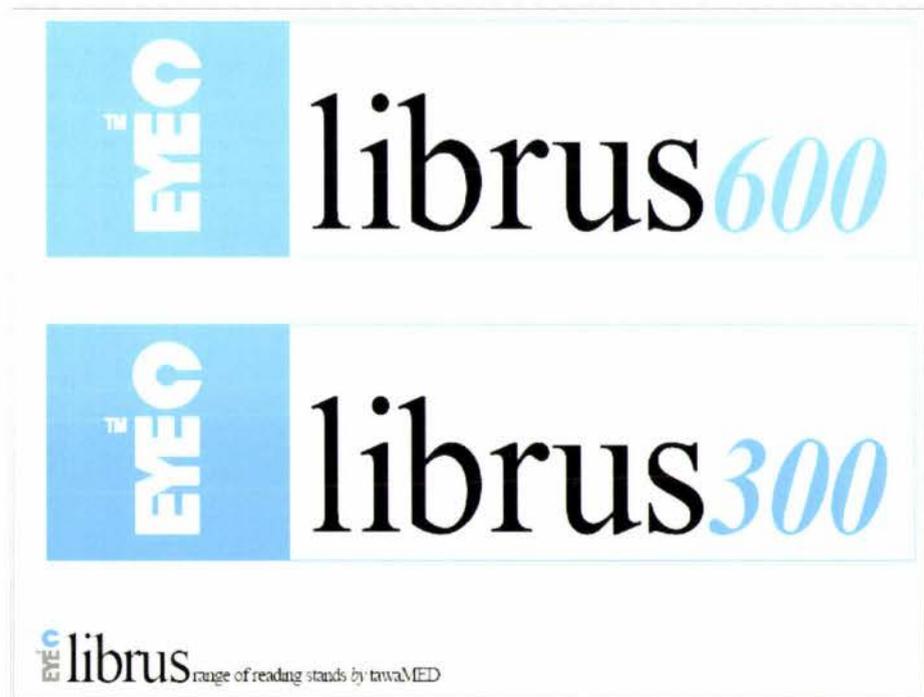


Figure 35. Librus Trademarking

5.12.3 Labelling

The Global Harmonisation Task Force [GHTF] comprehensively describes what should be included in labelling in the document 'Labelling for Medical Devices' Study Group 1 Final Document GHTF/SG1/N43:2005. ¹⁰⁸

For the all countries apart from the USA where compliance with Section 201(m) is required the GHTF policy would be appropriate. Examples of labelling are included in Appendix 8.

See also 5.6.4 & 5.7 Labelling for Electrical Safety and EMC, & See also Sec 5.17.4.5 FDA Labelling Policy – 210(k). ¹⁰⁹

5.13 Technical Files

5.13.1 Introduction

As previously noted in Chpt 4, Sec 4.4.1 and Fig 20, a Technical File [TF] must be created for compliance in the MD classification process and ultimately for conformity with CE or the Food and Drug Administration [FDA] of the USA.

5.13.2 Filing

The TF for the Librus development will be held as a hard copy and as electronic files, illustrated in Figure 36 below.

5.13.2.1 Notes:

Structure

This map is a reflection of the folder structure on C:\QMS\Technical Files\TF-Librus,

0. Contents thru to

8. Post Administrative Procedures.

Files & Folders

Where possible files will be archived in electronic form for the convenience of auditing the key documents in the folders above and will be in the TF as a hard copy. Records of conversations, emails and miscellaneous but relevant information from suppliers, will also be kept as hard copy. The flow of documents relating to the Technical File is detailed in Figure 36 below.

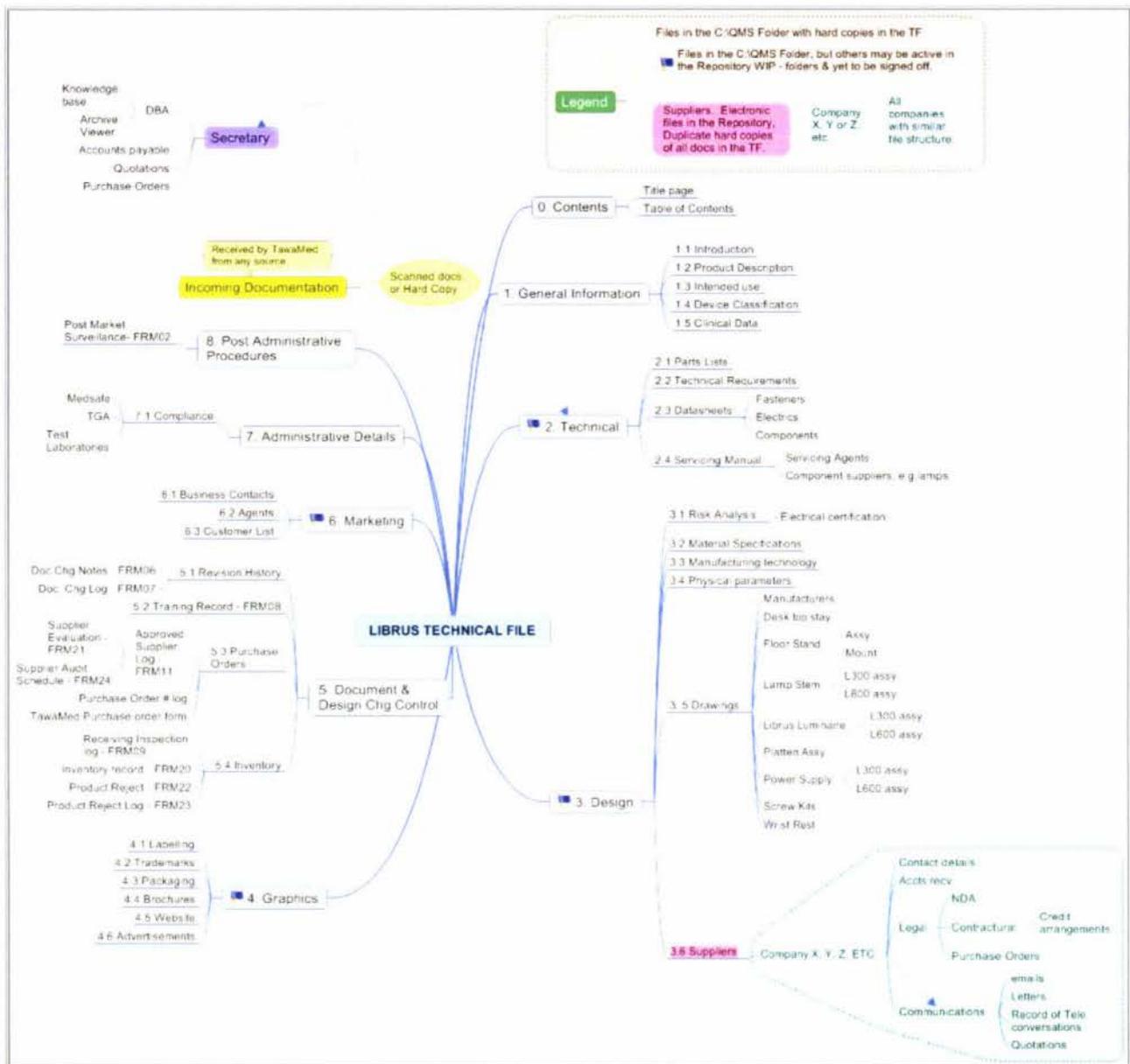


Figure 36. Librus Technical File

Document Handling

Every document associated with a particular supplier will be filed under that suppliers name, whether as a hard copy in the TF, or in the Repository\Supplier's folder. As documents will arrive from a variety of sources, it will be necessary to be vigilant about collecting all of them for scanning and allocating the paper or electronic copies to the correct binder or folder.

Table of Contents

The Table of Contents for the hard copy LIBRUS TF parallels the format of the C:\QMS – Technical File – TF-LIBRUS. See Figure 37. See also Figure 12, pp4.4.



Figure 37. Format of QMS + Hard Copy
Librus Technical File

5.13.2.2 TF Format

The format of the TF is described in SOP24 in the QMS file.

[LOCATION: C:\QMS\TawaMed QMS\QMS – SOPs\SOP24Iss02] See Appendix 9

5.13.2.3 Document Change Notes

Inaccuracies have been noted in the SOP24 file and to comply with the QMS, the modifications required a Document Change Note [DCN00101]. An example of the format has been included. See Appendix 10

5.13.2.4 Document Control

The QMS also specifies that documents must be controlled with procedures detailed in SOP07.

See Appendix 11

5.14 Define Technical Requirements

The Technical requirements for the Librus bookstands have been defined in Secs 5.2 thru 5.4 of this Case Study.

5.15 Proof of Concept Design

Three different models of the Librus bookstand have been fabricated to test concepts of manufacture, the distribution of light across the area of the stand and usability by a range of elderly people.

5.16 Production Prototypes

Apart from electrical components, the method of manufacture for all of the functional components, will be either by fabrication or CNC programmed press manufacture. Prototyping will also provide an opportunity to design assembly jigs and the wiring harness.

Initially it was anticipated that at least 10 units would be manufactured, including the vacuum formed luminaire housing. However if a change in the design of underlying structures is required, this will be reflected in modifications to expensive vacuum forming dies. As this component has no function in the assessment of usability, it will be omitted at the testing stage.

On further consideration it was decided that; 3 only Librus 600 and 2 only Librus 300 prototypes will be tested for a limited time with a variety of users instructed in their use. It is anticipated that their experience

will influence the design of the pre-production model. Drawings have been completed and prospective manufacturers approached for quotations. Initial approaches were a revelation:

Each required a different design input varying from Solidworks *.slddrw, *.parasolid, to *.pdf, AutoCAD Inventor and *.dxf. Complicating matters further was the fact that some manufacturer's had old versions of software that would not read files from our later versions. These input requirements related in part to the software of some of the CNC machines, but also the ability of production staff to interpret the files.

Although they had no claim to the IP, when one company redrew drawings to suit their infra-structural requirements and when we requested copies of these drawings to transfer onto the TawaMed title block to up-issue the drawing, this was refused!

There was no standardisation regarding the way the bends in sheet metal were handled. Some omitted the bend radius completely and then 'fudged' the outputs by trial and error. One had not realised the potential of a new machine and learned to programme it correctly.

Compound curves were generated more or less efficiently according to the range of tools loaded onto the turrets of the flat-bed presses.

Several were reluctant to quote; one suggested finally that they would advise us of their overheads and we were welcome to calculate a price - that they would decide to accept or not!

The implications for TawaMed are as follows:

1. These discussions will cause delays to market and illustrate infrastructural inefficiencies prevalent in NZ, SME manufacturers and a *lasse faire* attitude toward management of negotiations with prospective customers.
2. There are unacceptable inefficiencies introduced because of the re-drawing of suites of files to allow for the peculiarities of production methods and the inconsistency of machinery software and hardware. This is not unique to of course to MD developments, but presents similar issues for all product development in NZ.

In future all requests for quotations will include a statement to the effect that to comply with our QMS and the ISO requirements, they must submit their re-drawings and specifications to TawaMed for scrutiny and logging into our TF. If the labour for re-drawing is incorporated into the price, the supplier must declare the value and TawaMed will reserve the right to decide whose responsibility it will be to carry out the work and if it is appropriate.

- It is obvious that administration of multiple versions of files within a QMS and linking these to the relevant Requests for a Quotation, Purchase Order and BOM's may result in a manufacturing error unless TawaMed is absolutely vigilant tracking engineering production changes.

An analysis of experience of the Quotation and Purchasing process in NZ is illustrated in the following diagram. See Figure 38.

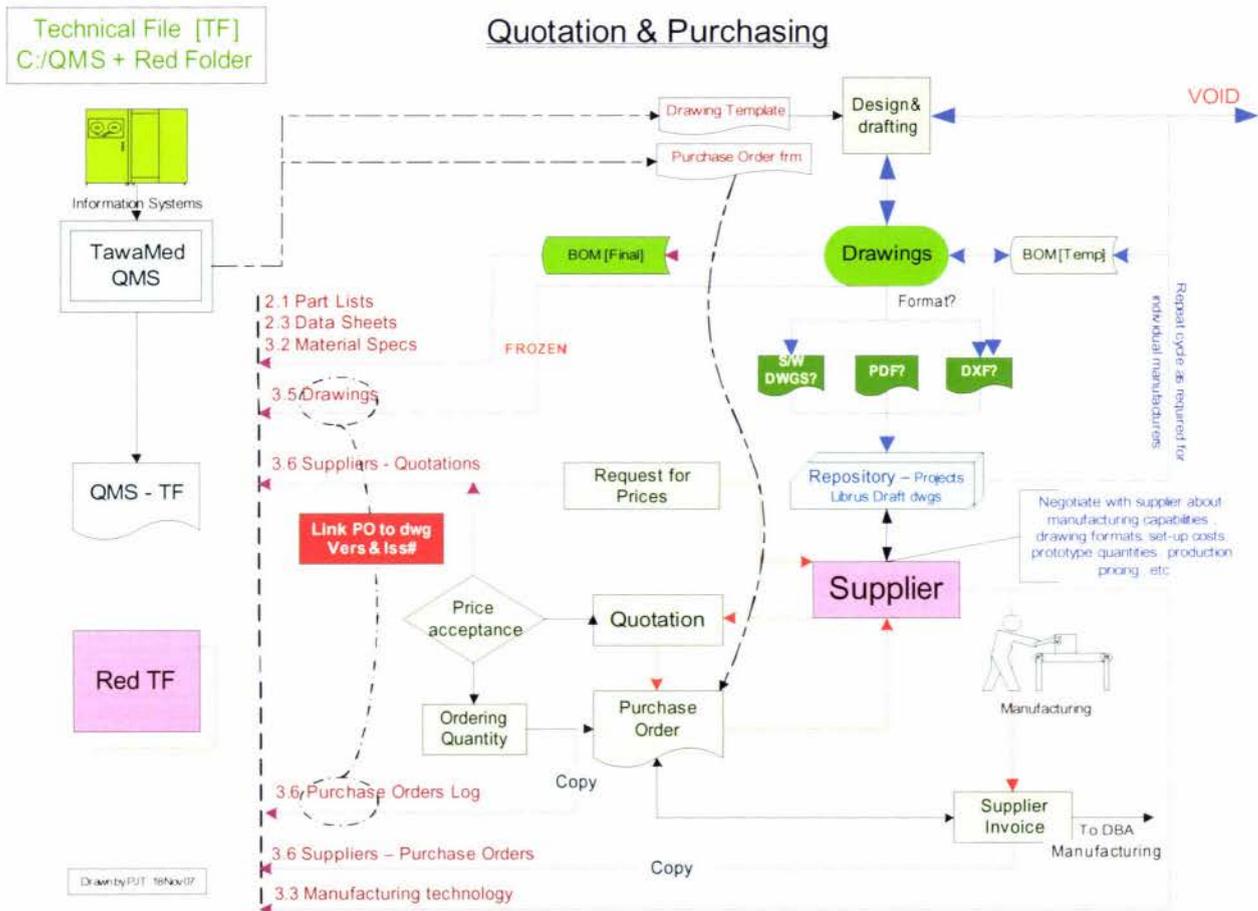


Figure 38. Quotation & Purchasing

5.17 Pre-production

The plan is to produce a limited run of about 100 units in the pre-production form, then conduct a more comprehensive survey of users for their observations about usability. Their feedback is likely to result in design improvements before full production and international marketing.

A view of the Production Prototype Librus 300 is illustrated below. See Figure 39, the LIBRUS configured as a Writing Tablet.

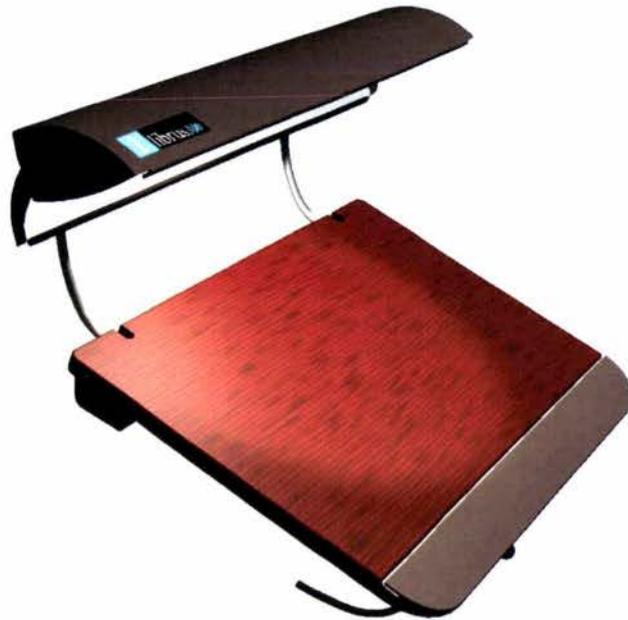


Figure 39. Librus 300 – Writing Tablet

See Figure 40, the LIBRUS in the reading position and showing the rear stay.



Figure 40. Librus 300 – Reading Stand

5.18 Compliance

The path to compliance has been described in depth earlier in this chapter. As stated previously the classification of the Librus products are at the lowest level - Class A.

5.18.1 WAND

Within 30 days of being placed on the market in New Zealand or exported, new MD's are required to be notified in Web Assisted Notification of Devices [WAND], the medical device notification database.

WAND will facilitate the management of recalls and safety alerts. The process is not complicated and the Key Steps are outlined on the following page. See Figure 41.

Key steps in completing a WAND medical device notification

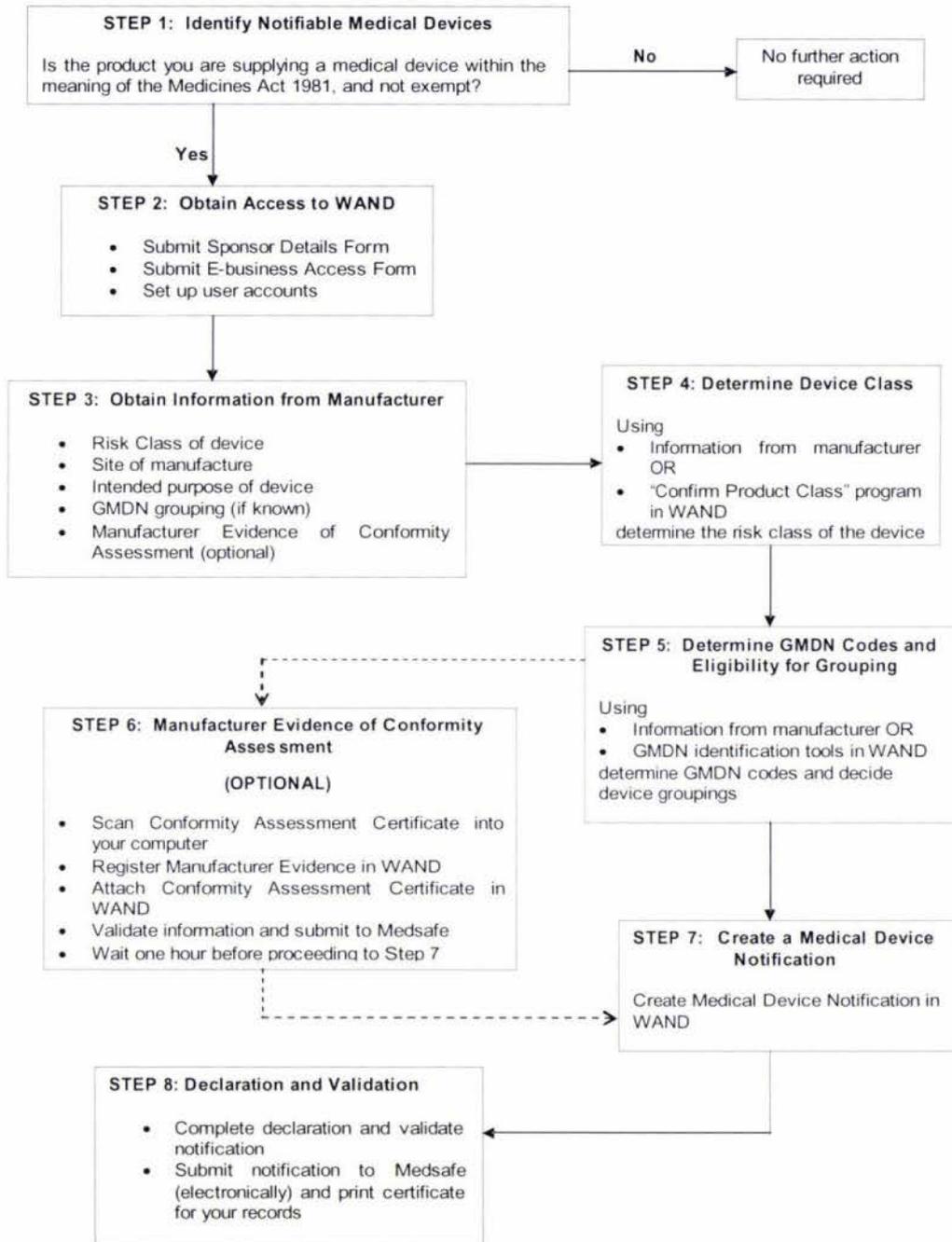


Figure 41. Key Steps in Completing a WAND Medical Device Notification ¹¹¹

The presence of a medical device entry on the database will NOT indicate approval or any other endorsement of the device by the regulator. ¹¹⁰

5.18.2 Harmonisation of NZ & Australia

The “Medicines (Database of Medical Devices) Regulations 2003” came into force on 1 January 2004. It was intended that their implementation would be the first step to the unification of the New Zealand Medical Devices [MEDSAFE] and Australian Therapeutic Goods Administration [TGA]. Many intermediate steps have been taken to introduce uniformity into the processes of the two countries and the next step was to introduce the Therapeutic Products and Medicines Bill. Because the Government was unable to achieve a majority to pass the bill, the creation of a common Agency to replace the MEDSAFE & TGA has been shelved.

In Australia, medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homoeopathic medicines and certain aromatherapy products are referred to as 'complementary medicines'. These are regulated as medicines under the Therapeutics Goods Act 1989 (the Act). Complementary medicines comprise traditional medicines, including traditional Chinese medicines, Ayurvedic medicines and Australian indigenous medicines. ¹¹¹

For unification of the systems of the two countries, it would have been necessary for NZ to conform to the standards and definitions of the Australian Therapeutic Goods Act 1989, rather than continue as at present, where there is no control on herbal, complementary medicines and so called dietary supplements.

The outcome is that to gain compliance for the Australian market, an independent application has to be made to the Device Electronic Application Lodgement [DEAL] system. See Figure 42. ¹¹³

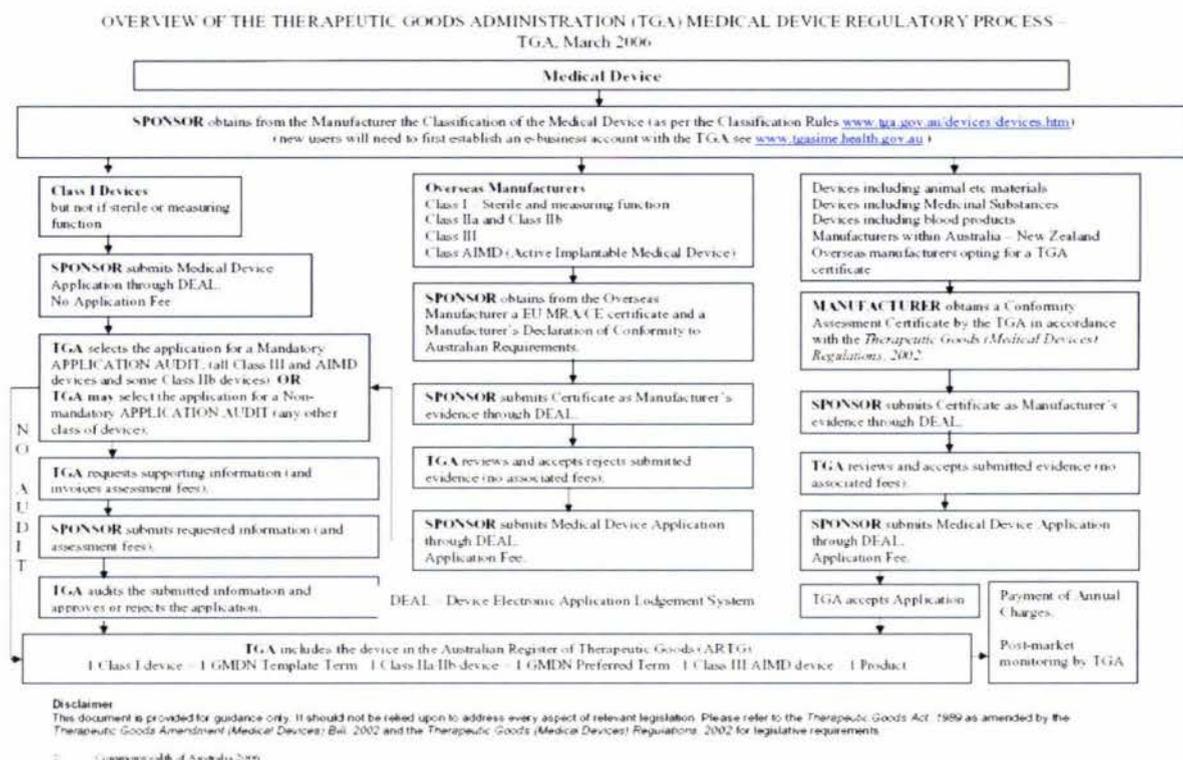


Figure 42. Device Electronic Application Lodgement [DEAL] System

5.18.3 DEAL

The DEAL system is more complicated than WAND and requires the manufacturer to issue a conformity certificate. In general terms, a medical device *manufacturer* [defined as] is the natural or legal person responsible for the design, production, packaging and labelling of the medical device and who represents themselves on the device labelling as the *manufacturer*. In addition, the *manufacturer* signs the Declaration of Conformity which states that the medical device meets the requirements of the *Therapeutic Goods (Medical Devices) Regulations 2002*. The *manufacturer* as described above may engage or subcontract other persons to carry out the realisation of the device under their control. ^{113 P}

P WHAT MANUFACTURERS REQUIRE A CONFORMITY ASSESSMENT CERTIFICATE

The following kind of medical device *manufacturers* are required under Australian Legislation to obtain a Conformity Assessment Certificate before the medical device can be included in the ARTG:

- All Australian *manufacturers*.
- Any *manufacturer* who manufactures medical devices containing materials derived from animal, microbial or recombinant origin.
- Any *manufacturer* who manufactures medical devices containing medicinal substances (substances that if used separately would be consider medicines).
- Any *manufacturer* who manufactures medical devices containing blood plasma derivatives.

Further the TGA requires that manufacturer's evidence be a obtained. See Box.

What is manufacturer's evidence?

Manufacturer's evidence is a certificate that demonstrates a manufacturer has been assessed (audited) and has the appropriate quality management system to manufacture medical devices at that site.

The manufacturer may have a variety of different certificates, however the certificates the TGA accepts as manufacturer's evidence are: European Union European Community Certificates (EC), TGA Conformity Assessment Certificates and Mutual Recognition Agreement (MRA) certificates.

Note: A certificate from the Food and Drug Administration (FDA) is not acceptable because it has been issued against a different auditing criteria to that required under the Australian legislation.

An International Standards Organisation (ISO) 13485 compliance certificate is not acceptable because does not provide assurance that the requirements of the Australian Regulations have been taken into consideration. ¹¹²

The Box above states that the TGA will accept as manufacturer's evidence the following

- European Community Certificates (EC);
- TGA Conformity Assessment Certificates; ^Q and
- Mutual Recognition Agreement (MRA) certificates.

An example of a European Union European Community Certificates (EC) is illustrated in Figure 43. ¹¹⁴

Q See *Therapeutic Goods (Medical Devices) Regulations 2002 – Part 4 – Regulation 4.1*

WHAT MANUFACTURERS DO NOT REQUIRE A CONFORMITY ASSESSMENT CERTIFICATE, PRIOR TO INCLUSION OF A MEDICAL DEVICE IN THE ARTG?

Overseas *manufacturers* not belonging to one of the categories described above and who hold current EC certification issued by an EU Notified Body under the EU Medical Devices Directive 93/42/EEC (MDD) or the EU Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) are allowed, under certain conditions, to use EC certificates to support an application for inclusion in the ARTG.

These *manufacturers* do not require a Conformity Assessment Certificate to be issued by the TGA prior to making an application to include the device in the Australian Register of Therapeutic Goods (ARTG).

See *Therapeutic Goods (Medical Devices) Regulations 2002 – Part 3 – Regulation 3.5* ¹¹³

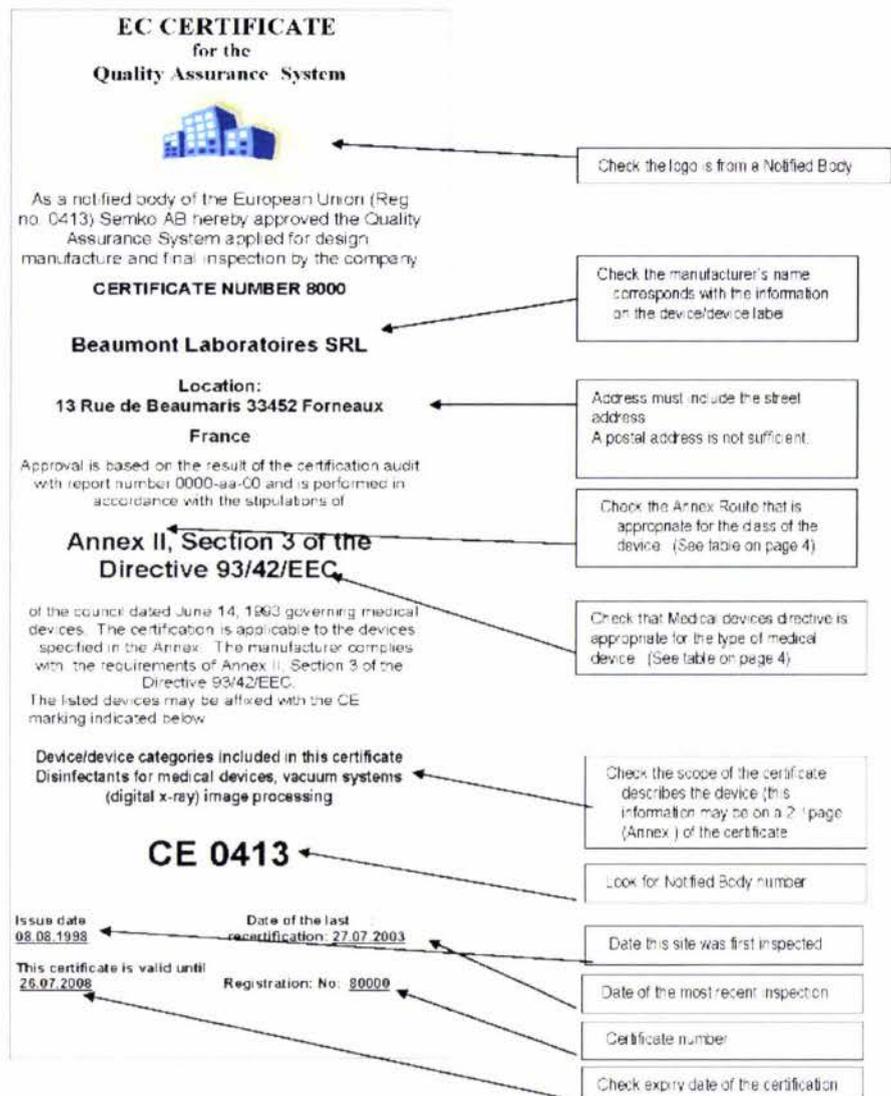


Figure 43. EC Certificate

Note that the Annex Route must be appropriate for the class of the device and the Certificate must be accompanied by an Annex. See Figure 44.¹¹⁴

Annex to certificate

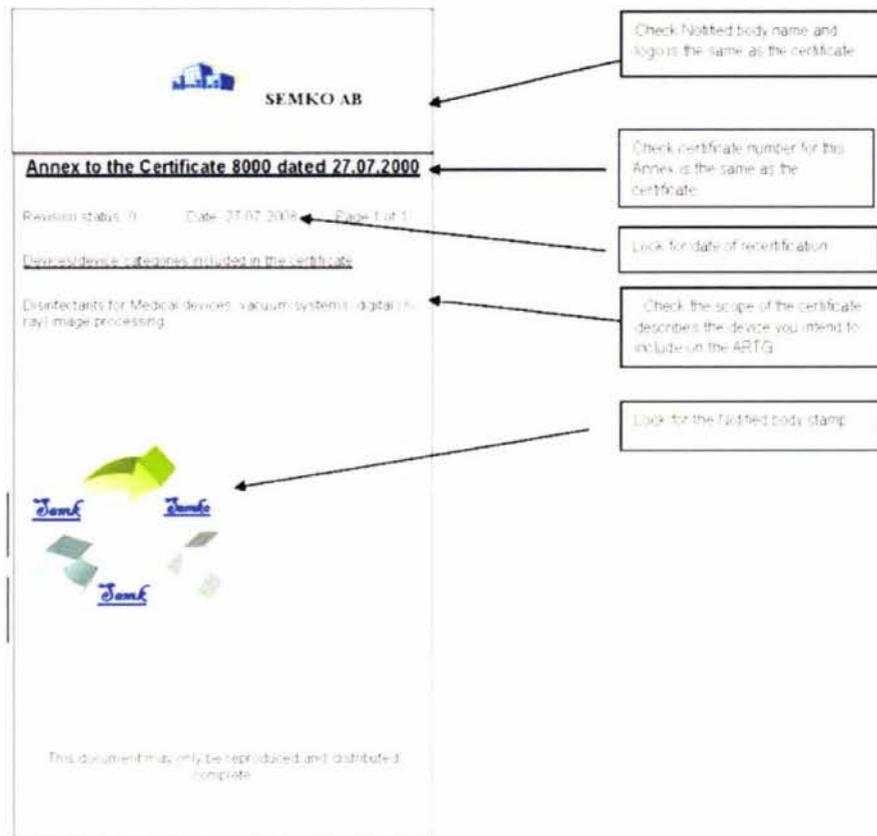


Figure 44. Annex to the EC

The appropriate Annex classification is found from Table 2 below:¹¹⁴

Below is a table which explains the appropriate European Union Device Directive and Annex for each class of device

| Classification | Option 1 | Option 2 | Option 3 | Option 4 | Directive |
|-----------------|-------------------|---------------|-----------------|-----------------------------|------------|
| Class 1 Measure | Annex II 3 | Annex V | Annex IV* | Annex VI | 93/42/EEC |
| Class 1 Sterile | Annex II 3 | Annex V | n/a | n/a | 93/42/EEC |
| Class IIa | Annex II 3 | Annex V | Annex IV* | Annex VI ^T | 93/42/EEC |
| Class IIb | Annex II 3 | Annex V + III | Annex IV + III* | Annex VI + III ^T | 93/42/EEC |
| Class III | Annex II 3 + 11.4 | Annex V + III | Annex IV + III* | Annex VI + III ^T | 93/42/EEC |
| AIMD | Annex 2.3 + 2.4 | Annex 5 + 3 | n/a | n/a | 90/385/EEC |

^T Indicates that this option may only be used if the device is supplied non-sterile

* Indicates that this option may only be used if the device is supplied non-sterile and only 1 batch is included in the certificate

Table 2. Classification of MD's by Annex

If the manufacturer has not obtained an EC, then a TGA Conformity Assessment Certificates may determine the route for conformity by consulting the Table 3.¹¹⁵

ATTACHMENT 2. CHOICES OF MINIMUM CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICES OF A PARTICULAR CLASSIFICATION

| Classification of Medical Device | Minimum Conformity Assessment Options | Conditions on Options |
|----------------------------------|--|--|
| Class I | Part 6 | |
| Class I Sterile | Part 6 + Part 4 | excluding declaration of conformity to Part 4 |
| Class I Measuring | Part 6 + Part 3 | excluding declaration of conformity to Part 3 |
| | or Part 6 + Part 4 | excluding declaration of conformity to Part 4 |
| | or Part 6 + Part 5 | excluding declaration of conformity to Part 5 |
| Class IIa | Part 1 excluding Clause 1.6 (Design examination) or Part 6 + Part 3 | For non sterile medical devices, excluding declaration of conformity to Part 3 |
| | or Part 6 + Part 4 | Excluding declaration of conformity to Part 4 |
| | or Part 6 + Part 5 | For non sterile medical devices, excluding declaration of conformity to Part 5 |
| Class IIb | Part 1 excluding Clause 1.6 (Design examination) or Part 2 + Part 3 | for non sterile devices |
| | or Part 2 + Part 4 | |
| | or Part 2 + Part 5 | for non sterile devices |
| | | |
| Class III | Part 1 or Part 2 + Part 3 or Part 2 + Part 4 | for non sterile devices |
| | | |
| | | |
| Class AIMD | Part 1 or Part 2 + Part 3 or Part 2 + Part 4 | for non sterile devices |
| | | |
| | | |

Table 3. Conformity Assessment by Classification.

The assessment option is then followed on the flow diagram.¹¹⁵ See Figure 45.

ATTACHMENT 1. OVERVIEW OF CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICES OF A PARTICULAR CLASSIFICATION

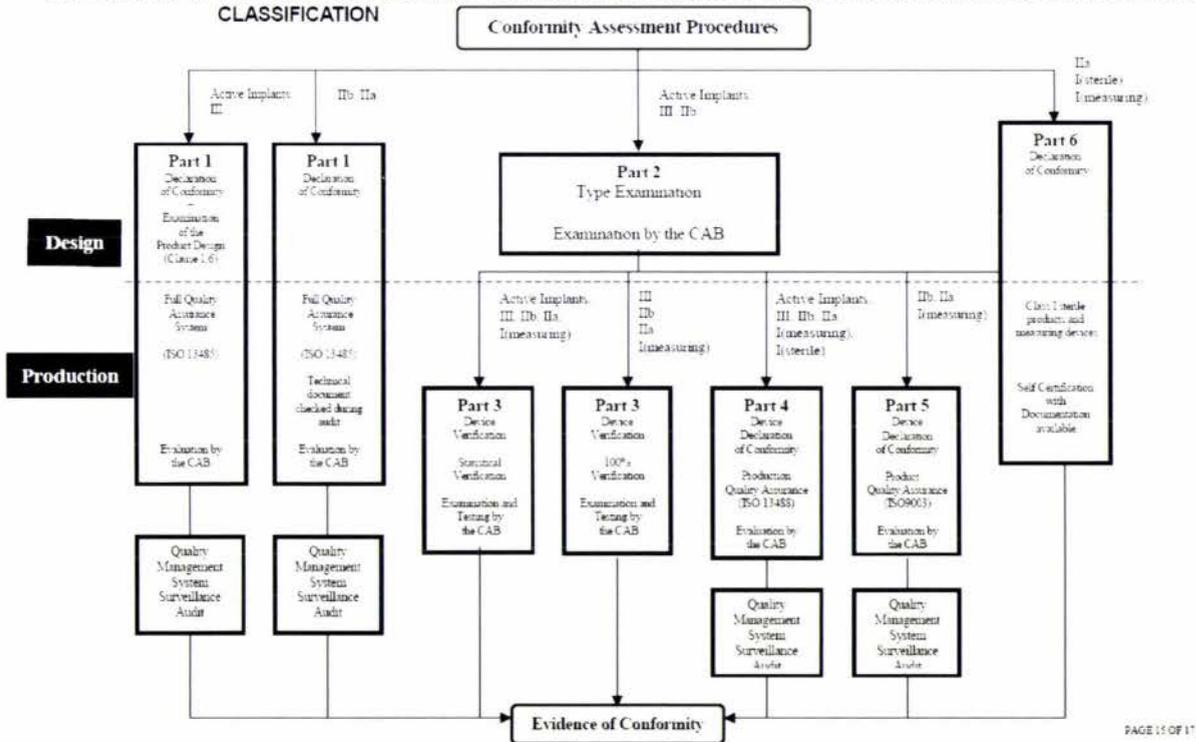


Figure 45. Conformity Assessment Procedures

It will be apparent from Fig. 42 that the Librus products will be follow the simplest route, i.e. Part 6, nor will they require a Conformity Certificate.¹¹⁵ See the marked section in Figure 46 below.

ATTACHMENT 3. KINDS OF MEDICAL DEVICES WHICH REQUIRE A CONFORMITY ASSESSMENT CERTIFICATE FROM THE TGA

| Kinds of Medical Devices | TGA Conformity Assessment Certificate required |
|---|--|
| Medical devices manufactured in Australia | Yes |
| Medical devices, manufactured outside Australia, containing non-viable tissues of animal origin, other than those intended to come into contact with intact skin | Yes |
| Medical devices, manufactured outside Australia, containing tissues, cells or substances of microbial or recombinant origin and are intended for use in or on the human body | Yes |
| Medical devices, manufactured outside Australia, incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device | Yes |
| Medical devices, manufactured outside Australia, that incorporate, or are intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device | Yes |
| Class I medical devices, or the manufacturers of Class I medical devices, not intended to be supplied in a sterile state or that does not have a measuring function | No |
| Examples of manufacturers of exempt devices | No |
| Medical devices approved under section 41HB of the Act or manufacturers of medical devices approved under section 41HB of the Act (ie for use in the treatment of another person or for use solely for experimental purposes in humans) | No |
| Medical devices subject to an authority under section 41HC of the Act or manufacturers of medical devices approved under section 41HC of the Act (ie authorising a specified medical practitioner to supply specified kinds of medical devices for use in the treatment of humans to a specified class of recipients) | No |

Figure 46. Conformity Certificate Criteria

5.18.4 Food and Drug Administration of the USA [FDA]

5.18.4.1 Introduction

For entry into the USA, compliance becomes far more complicated and expensive.

The consequences for not following the correct procedures are dire, but there are some facilities available from the Food and Drug Administration [FDA] itself to assist Small Manufacturers. [Their definition of small seems to be in the order of <\$30M sales!] The Division of Small Manufacturers Assistance (DSMA) directs a program to provide technical and other non-financial assistance to small manufacturers of medical devices and radiation-emitting products to promote understanding of and compliance with applicable laws

and regulations. The following is an extract from **Device Advice**.¹¹⁶

'One of the most difficult aspects of getting a medical device to market in the US is knowing where to begin i.e., what are the steps for marketing and in what order they are to be taken. Essentially, medical devices are subject to the general controls of the Federal Food Drug & Cosmetic (FD&C) Act which are contained in the final procedural regulations in Title 21 Code of Federal Regulations Part 800-1200. These controls are the baseline requirements that apply to all medical devices necessary for marketing, proper labeling and monitoring its performance once the device is on the market. 21 CFR Parts 800 - 1299.

5.18.4.2 Three Steps to Obtaining Marketing Clearance from CDRH are defined by:¹¹⁶

"Is it a MD?"

***Step one** in the marketing process is to make absolutely sure that the product that you wish to market is a medical device, that is, does it meet the definition of a medical device in section 201(h) of the FD&C Act. For example, the product may be a drug or biological product that is regulated by a component in the FDA other than the Center for Devices and Radiological Health (CDRH) and for which there are different provisions in the FD&C Act. Or your product may be a medical device and is also an electronic radiation emitting product with additional requirements.*

Classify Your Device

***Step two** is to determine how FDA may classify your device - which one of the three classes the device may fall into. Unless exempt, FDA will classify your device. Classification identifies the level of regulatory control that is necessary to assure the safety and effectiveness of a medical device. Most importantly, the classification of the device will identify, unless exempt, the marketing process (either premarket notification [510(k)] or premarket approval (PMA)) the manufacturer must complete in order to obtain FDA clearance/approval for marketing.*

Selecting the Appropriate Marketing Application

***Step three** is the development of data and/or information necessary to submit a marketing application, and to obtain FDA clearance to market. For some [510(k)] submissions and most PMA applications, clinical performance data is required to obtain clearance to market. In these cases, conduct of the trial must be done in accord with FDA's*

Investigational Device Exemption (IDE) regulation, in addition to marketing clearance."

5.18.4.3 A 510(k) ¹¹⁸

'Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). There is no 510(k) form, however, 21 CFR 807 Subpart E describes requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.'

'A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate. Legally marketed also means that the predicate cannot be one that is in violation of the Act.'

Fees

The review fees for 510(k) submissions are below:

| 510(k) Review User Fees (U.S. Dollars) | | |
|---|---------------------|---|
| | <i>Standard Fee</i> | <i><u>Small Business Fee</u> (< \$100 million in annual sales)</i> |
| FY2007 (Oct. 1, 2006 - Sept. 30, 2007) | \$4,158 | \$3,326 |

5.18.4.4 Premarket Approval ¹¹⁸

'Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.'

For a more information about the Premarket Approvals see Appendix 12.

5.18.4.5 Other Requirements Besides Marketing Clearance ¹¹⁶

Premarket Requirements: Labeling, Registration, Listing

'Before marketing clearance is obtained the manufacturer must assure that the device is properly labeled in accordance with FDA's [labeling](#) regulations. Once clearance for marketing is obtained, the manufacturer must register their establishment and list the type of device they plan to market with the FDA. This [registration](#) and [listing](#) process is accomplished by the submission of FDA Form 2891 and 2892.'

Labelling

Section 201(k) defines "label" as a:

- *'display of written, printed, or graphic matter upon the immediate container of any article...'*

The term "immediate container" does not include package liners. Any word, statement, or other information appearing on the immediate container must also appear "on the outside container or wrapper, if any there be, of the retain package of such article, or is easily legible through the outside container of wrapper.'

Section 201(m) defines "labeling" as:

- *'all labels and other written, printed, or graphic matter*
 - a. upon any article or any of its containers or wrappers, or*
 - b. accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce'.*

The term "accompanying" is interpreted liberally to mean more than physical association with the product. It

extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. "Accompanying" also includes labeling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

5.19 Develop Service Network

With few moving parts, no mechanical components to wear and only a limited number of electrical parts, servicing issues of any significance are unlikely to arise from the Librus development.

The general public are familiar with installing replacement fluorescent lamps, the only fragile and limited service life component. Instructions for replacing the lamp are simple and will be included in the operating manual. Other electrical repairs if they are required, will not tax any electrical appliance service person. For these reasons it will not be necessary to establish a formal Service Network. Documentation for servicing will be available from the Website and accessible by email directly, or through a Customer Relationship Management [CRM] programme integrated with the site. See Chpt 6. A NZ Model.

Distributors will be briefed about servicing documentation; parallel sets will be held on the Website and in the Technical File and QMS.

5.20 Marketing & Distribution

5.20.1 Product Colour Schemes

There is only one component for each of the two models that can be coloured, as the Stainless Steel components will be left unpainted and the bookstand must be a dark, matt colour to reduce glare and reflections into the eye of the reader. Castings will be powder coated with textured finishes to hide blemishes.

The colour of the luminaire housing drawn from vacuum formed ABS, will reflect the needs of the end user and their environment. Frequently used in a domestic situation, the Librus 600 will be softened with a pastel colour, whereas the Librus 300 will appear more clinical.

5.20.2 Branding & Trademarking

Branding will be enhanced in the Website, modified and extended for the packaging, brochures, leaflets, advertisement copy and point of sale displays. See also: Chpt 5.11 Trademarking & Branding

5.20.3 The Website

The Website is intended to provide information about product, the Company and the environment within which the products will be used. Three divisions will be structured for access at different levels by the professions and the public and integrated with a CRM programme – discussed further in Chpt 6.

Opportunities will be provided in the CRM inviting responses to FAQ's.

The home screen will be in three blocks; the first linked to information about the company, it's mission, future developments, personnel, contact routes, etc. The second will provide links to other information and technical sites, especially at this stage to those related to visual disorders and the third to the product specifications and availability, etc.

5.20.4 Target Markets

By relying for international interest to be generated, at least initially from the Website, it is hoped the risks imposed by unexpected demand will be controllable and contractual issues with Distributors will not have to be addressed. The local market [including Australia] is likely to be substantial, particularly for the Librus 600 as it is aimed at the aging population, a far larger market than the professional market for the Librus 300.

The Users may be marketed directly through advertisements appearing in newsletters and magazines published by organisations such as Age Concern and Grey Power. Low Vision Clinics are significant marketers of Low Vision assistive devices, as are some interested Ophthalmic practitioners.

The Royal NZ Foundation of the Blind market directly to their membership. Project Enable provides Aids and Appliances to those in need who are approved by Accredited Assessors and a number of companies market assistive devices to the disabled.

There are over 900 Pharmacies throughout NZ, and a Point of Sale stand is planned to display the Librus 600 at the entrance to the shop. If the device was illuminated, it would immediately be attractive, self promoting and invite a trial use for the elderly entering the shop.

The Librus 300 is aimed at the professional End User, the Ophthalmic practitioner; most frequently targeted at Conferences where trade displays feature.

Ultimately the potential market to professions and trades that involve colour matching and discrimination tasks will be addressed.

5.20.5 Price Sensitivity

With the emphasis on value and functionality, price sensitivity should be less of an issue, especially if there are no competitors, at least initially. A price structure will reflect a margin that might be expected by a distributor, however there will be a heavy emphasis on direct marketing to retain profit within the company.

5.20.6 Training

The Users/End Users will be targeted differently for each product. Very careful thought will be put into the ergonomics of the instruction sheets sold with the products. Further information will also be available through the Website about the functioning and use of the devices.

If pharmacies become significant sales outlets, their staff will require some training to support the printed material. Low vision practitioners will train their patients in the use of the devices.

5.20.7 Advertising

Advertorials provide an entry into a number of professional journals and new instruments are often 'written up' by users. This might of course be a negative, critical appraisal! Advertising will be limited and targeted as indicated by initial sales.

5.20.8 Post Market Evaluation

Reported observations by and visits to practitioners, will be a valuable source of information about user experience. Emailed questionnaires or surveys of users will also be considered.

5.21 An Alternate Development Process

The development of the Librus MD's has reinforced the fact that the process has numerous hurdles, many of which were crossed unnecessarily as a result of inexperience.

Alternative models for managing the process will be addressed next in Chapter 6. A NZ Model.

6. A Model for Medical Device Development in New Zealand

6.1 Objective

To develop management and organisational models that could facilitate the translation of ideas for medical devices into reality.

6.2 Introduction

New Zealand is ideally placed to develop a medical and assistive device manufacturing base, producing high value, limited volume technology.

As discussed in Chpt1.3, population and epidemiological trends favour growth in this manufacturing sector. There include

- demands of an aging population expecting to retain functionality and independence in their own home until near death;
- problems of lifting, transporting and caring for an obese population and the associated regulatory constraints on lifting and handling of patients; and
- increases in the prevalence of the diseases of affluence and aging, with chronic illness sustained by improved health care. e.g. obesity, diabetes, rheumatoid arthritis & stroke.

Other drivers include elective procedures that can be afforded by an increasingly affluent population to restore functionality, reverse the effects of aging and increase physical performance.

6.3 The Source of Ideas

As previously pointed out in Chpt 2 ideas for MD's are generated within existing manufacturers by embracing advances in technology. Suggestions for a revised marque or a re-engineered new product may come from within the organisation's engineers, technologists, or from marketing personnel responding to the demands or suggestions of users/end-users.

There are three obvious sources of ideas for radically improved or unique New Products:

Academic research institutions.

Health professionals.

Hospitals and treatment centres.

6.3.1 Academic research institutions

As discussed in Chpt 3.2 Sharing IP – Technology Transfer, academic research institutions rarely evolve research output into commercial products because their culture and infrastructure does not encourage such developments. Exceptions are the commercial arms of NZ Universities who have successful business models, however business failures have occurred with organisations such as IRL when they have attempted commercial developments.

Even for the Universities it will have been a difficult transition to commercialism, for as Sahin 2006¹²⁰ states:

'The researcher lives in a world of conflict. Their career depends on research and publication. Many implicit rules of academia allow them to go only so far. They are experts in the technology associated with the innovation, but not on many of the other technologies that might be needed to create commercial success.'

In other words, their incentives go in the wrong direction and there is serious competition for and limitations on their time. Furthermore, they have limited knowledge of both the commercialisation process and the enabling surround technologies.'

Can they be expected to devote their time to academically unrewarding tasks of developing a manufacturability prototype? To utilise the expertise of academics and students is logical, but presents some organisational challenges.'

Teaching usually takes priority and at exam time, marking papers will conflict with commercial imperatives.

Bridging the innovation gap will not be achieved simply by placing companies close to sources of research. A commercial imperative is incompatible with the laissez-faire approach of some academics who may be disorganised, casual about accountability for work hours and digress off at tangents during the course of day to satisfy their inquisitive mind. A fundamental cultural shift is required to share ideas with commercial organisations, reduce institutional bureaucracy and improve efficiency. "Doing it the Kiwi way" is out of touch with global realities and while so called 'lifestyle choices' sound and are attractive, the NZ economy will continue to stagnate and ultimately falter if we continue on the present path.

There may also need to be a change of focus of the administration of academic institutions to accommodate the commercial imperatives of high risk innovative projects. They must recognise that in backing a project, they might sustain a loss!

The resource of machinery and technology in institutions is under utilised. Health, safety and security issues should be resolved to authorise staff and students to use capital equipment outside teaching hours for an approved project. This has been done successfully at the Massey University School of Design.

Subject to proof of competency and agreement to abide by the rules and regulations of the organisation, a project sponsor should also be able to work alongside, or even independently on certain projects within an academic facility. After all a multidisciplinary learning institution should be a perfect environment within which to foster the synergies required for a mechatronics development, however from the author's experience of attempts to interact with them, they are really not interested in collaboration.

The costs of operating academic organisations are largely standing overheads. To charge out the use of capital items at 'commercial' rates for a high risk, private R&D is illogical for a public utility. The author has had the experience of paying the going rate of \$160/hr for each of two researchers to be briefed on a subject that was peripheral to their knowledge base. Only when they gained further insight into their own technology could they understand what was expected of them to solve the problem they were presented with. Should the client have to pay to educate the contractors?

The imperative to spend surplus funds at the end of the budget period for capital items leads to mismanagement and a waste of resources. Budget surpluses should be carried forward and have no bearing on the allocation for perhaps four years, then a review considered if funds have been inappropriately utilised. As a nation of small businesses, we cannot afford the luxury of duplication of specialised services, even if the geography of the country requires more travelling to access them. Internet access, enabling instant collaboration, virtual design and manufacturing should radically facilitate the R&D process.

'NZ Inc' should be encouraged to establish high technology industries by Government utilities granting direct access to appropriate resources. Not necessarily through funding to pay for them, but instead by for example, granting 'units' of resource allocation [e.g. green dollars?] against contracts to share in commercial returns from successful projects.

6.3.2 Health Professionals

Health professionals, in particular surgeons who as a result of years of experience, are able to describe more expedient or efficient procedures, tests & instruments. However they usually cannot, for one reason or another, translate the idea into a commercial reality:

- They may not have the time or commercial resources to pursue the development.
- A critical technological element may be necessary to 'bridge' the gap, requiring a research

component.

- There are few design groups that could undertake such developments in New Zealand.

Student and post graduate projects have been suggested as a solution to resolving some technical issues. However the timetable of the student invariably does not coincide with the project plan, nor do they have the experience to develop an idea without very close supervision. The student may not produce the desired outcome either in terms of quality, or before they leave the institution. Continuity and meeting objectives in a project are essential. If students are utilised, there must be a commitment by staff of the institution to undertake the completion of a project, correct errors or omissions, etc.

6.3.3 Hospitals & Treatment Centres

There is an obvious extension of the link between the Health Professional and innovation in MD development. A link between industry and Hospitals and Treatment Centres would facilitate MD development in NZ.

From personal experience of the author, the hospital service not only fails to learn from medical misadventures, but does not to seize the opportunity to turn the event into a commercial advantage. The focus of efficiency is generally on cutting costs; rarely is any consideration given to modifying technology to control hazards or to designing for increased patient satisfaction and safety. Consider the following

- facility design is lead by architects and while there is extensive consultation with health care professionals, they are not experts in aspects of design beyond their clinical understanding. Design can be manifestly improved if other professionals such as ergonomists, illumination and environmental engineers are involved; See [Example 1](#)
- at the facility design stage, budget constraints result in shortcuts that must be paid for by a loss of efficiency over the life of the facility; and
- high staff transfer and turnover leads to a lack of continuity of policy and a loss of institutional intelligence.

There is a lack of integration between facilities, MD's infrastructure, IT, etc. For example high tech equipment requires a controlled environment, special furniture, etc. Because of structural limitations of facilities, compromises are frequently made with installations and repairs.

There is no mechanism or process for staff to advocate design improvements, or to provide them with an outlet or reward for introducing ideas for technology development. In addition, because of their lack of

appreciation about design, how it relates to patient safety, or because of defective policies, staff do not take any initiative to improve the environment. See [Example 2](#) below.

Design Deficiencies: Example 1

Virtually all facilities illuminate open areas with uniformly spaced fluorescent luminaires installed to the minimum standards of codes of practice. Little consideration is given to the ultimate use of that space, or to the specific requirements of demanding tasks within it.

Maintenance of the system is generally in response to a failure, rather than to the decline in efficiency over the lifetime of the lamp.

In a state of perpetual compromise, the intensity of illumination is frequently insufficient to perform fine detail tasks safely and efficiently; inappropriately positioned sources cast shadows over tasks and poor colour rendering lamps may distort the colour appearance of skin tones, leading to faulty clinical judgments.

The ramifications of poor design are far reaching in all sectors of the health service, not just the public hospitals. In the private hospital sector, including residential care and retirement villages, patient handling is a consistent problem, reflected in the ACC statistics and increasingly problematic with increasing morbidity in an aging, diabetic and obese population. Slips, trips and falls are a significant cause of morbidity and acute admissions.

Design Deficiencies: Example 2

The purpose of the medical instrument sterilising facility in Wellington Hospital is to initially clean every instrument of any biofilm and subsequently sterilise and package the instruments for use in the operating theatre. The instruments are layered in trays that are difficult to handle because of their weight and the height of the benches. The facility is generally staffed by middle aged women whose close work vision is no doubt compromised because of their age, but few if any of them appear to wear any optical correction. The illumination is inadequate for the task and degraded by multiple reflections from stainless steel surfaces.

Many of these surgical instruments, particularly those used for microsurgery have fine and delicate surfaces or appendages that are difficult to clean and are easily damaged. The annualised cost of the damaged instruments far outweighs the cost of improvements, but the funds come from a different budget; the losses can be hidden and therefore managed.

In the operating theatre instruments are rejected when staff discover them to be contaminated, despite cleaning and sterilisation. If the rejected instrument is 'one of a kind' this may be critical to the efficiency of the surgery.

An opportunity exists for mechanising the instrument handling processes to minimise lifting and instrument damage. Visual inspection processes could be manifestly improved by imposing visual standards on the operators and viewing the instruments with inspection devices that control the illumination and magnification of contaminated surfaces.

6.4 The Initiation Process

In Chpt 4, the process of a MD development was considered. See Cl 4.4.1, the MD R&D process.

However long before the process commences, a number of stages or events occur; in the beginning there is an idea! Then:

1. Depending upon the knowledge of the sponsor, they might develop the idea with drawings/sketches, descriptions, aims and objectives for the device, proposed market, price they would pay for the device, etc.
2. They might approach a friendly engineer, academic, or other knowledgeable person for advice about 'where to from here?'
3. The chances are that the advice they receive will have been critical, as some self-evident issues are revealed by the expert confidant; the sponsor will retreat to give the matter further thought.
4. If they are not daunted, the sponsor may then provide some answers and a further meeting might result in suggestions about who to approach next, or the expert may wish to be more actively involved.
5. If the invention is simple, requiring only basic approvals with minimum compliance, then conventional manufacturing processes may result in a satisfactory NPD.
6. If the proposed MD has a higher classification and is complicated by compliance issues, the process of development in NZ may take so long, or be so inefficient, that it effects the profitability of the venture.
7. If any pure or applied research is required to to solve technical issues, the chances are that the inventor will take their idea offshore.

6.5 Constraints of the NZ Micro-enterprise

The preceding chapters have detailed a complex array of processes for a MD development that to conduct successfully and efficiently, require a considerable diversity of skills, certainly not accessible within the majority of NZ organisations that by world standards are not even SME; they are actually Micro-Enterprises[ME's]. These skills must include technology, quality management, compliance regulations, knowledge of standards, intellectual property law, materials science, electronics, ergonomics, etc.....the list is extensive, especially for complex diagnostic devices.

To manage this diversity in itself requires a skill that would be most unlikely to be found in an 'inventor'. In fact it is almost a cliché that for a development to succeed that the inventor must be separated from the process.

There is a need for a radically different business structure/model for a MD development to succeed in NZ.

6.6 The Innovation Gap

To bridge the innovation gap, Sahin 2006, suggests the following model ¹¹⁹ See Figure 44.

Figure 44. The Innovation Model



Stage 1 companies (sources of innovation) may be viewed as big **R**(research) and small **d**(development), or **R&d**

Stage 3 companies (the implementers/manufacturers/marketers) as small **r**(research), small **d**(development) and big **D**(delivery).

The facilitators are:

Stage 2 companies as small **r**(research), big **D**(development) and small **d**(delivery)

A few such companies exist. Sahin is the founder and CEO of TIAX LLC. ^R Batelle,^S and Sarnoff ^Tare two further outstanding examples of Stage 2 companies.

No such organisation exists in NZ and it would not be justified for one to be established, however a model that incorporates many of the features of a Stage 2 company would be feasible. The first option to be considered is a joint venture.

R <http://www.tiaxllc.com/>
S <http://www.battelle.org/>
T <http://www.sarnoff.com/>

6.7 Joint Venture

A joint venture is contractual agreement joining together two or more parties for the purpose of executing a particular business undertaking. All parties agree to share in the profits and losses of the enterprise. Unlike a partnership the joint venture is generally for one specific project only, rather than for a continuing business relationship.

A joint venture was proposed by the author to IRL, a highly resourced organisation, to develop a visual performance assessment MD. As the concept involved materials science, as well as electronics, development of sensors and associated software to measure electro-physiological functionality of vision, it appeared to be an ideal project for their scientists to be involved in.

The proposed instrument was of high value, with an international market potential and justifying a significant investment in R&D. However the author could not afford to pay the organisation's going rate for R&D. In fact one could argue that the rates were set at an unrealistic level; they appeared to be based on a return on material and intellectual capital, rather than taking a broader view that as a state asset, they could make a very significant contribution to the public good, i.e. through NZ Inc.

A model was proposed that deferred income to IRL by assigning value to inputs of intellectual capital by a system of credits. The value of the credits contributed by each party would then be offset against the profits and losses.

To establish a system to assign a value of a credit to the project would require some discussion. It might be established as equivalent to the product of an hourly rate and the time spent on the service but only, if as discussed above, the hourly rate was realistic.

There would need to be considerable goodwill between the parties to establish a workable system and the initial project might not run smoothly, however the returns for both parties and ultimately for the benefit of others could be considerable.

An alternative proposal was to agree at the outset to share in the profits of the outright sale of product, through a royalty, or from licensing fees if the technology was sold to a third party. Any of these ideas were apparently too innovative for them to accept; they need a cultural shift and more professionalism.

Continuing to develop policy around traditional models may be self satisfying, but it is not the way of the future.

6.8 The 'Virtual' Organisation

In Chapter 4 and 5, a QMS was discussed and a Case Study presented to illustrate the application of these processes.

Apart from communications using email, phone and the internet server Servage, the author's 'virtual' structure – a 'hub' of experts meet at two regular times each week. Broadly the agenda is to:

- Conduct a design review of existing projects.
- Allocate tasks to it's members to further the objectives of the projects.

If the technology is outside the competency of members of the 'hub', resources may be called upon with expertise in:

| | |
|--|---|
| Quality, project and fiscal management | Electronics |
| Compliance regulations | Ergonomics/Human Factors Design |
| Intellectual property law | Embedded software |
| Technology innovation and design | High level software |
| Industrial design | Website design |
| Materials science | Technical writing, training on-line and seminar education |
| CAD | Product testing |
| Optics | Consumer evaluation |
| Illumination engineering | Production & Manufacture |
| Instrument construction and testing | Marketing & Distribution |

This above list is by no means exhaustive!

What has been missing is consultation with users/end-users during the development process. The sponsor may of course be an user/end-user, however they will generally be too close to the project to be truly objective in their assessment of a development. An example of this distortion in perspective is the implantation of an intra-ocular lens following a cataract extraction.

The shared goal of the clinician (user) and the patient (end-user) is the restoration of sight. However the evidence of improved sight from the perspective of the clinician and the end-user is necessarily derived from different methods of data capture.¹²⁰ The clinician objectively measures parameters such as residual

refraction and visual acuity to demonstrate a successful outcome. The subjective end-user reports may however reveal important symptoms of visual disturbance, such as sensitivity to light or a difference in image quality between the eyes; performance factors which are not necessarily revealed through objective measurement. Thus, to understand end-user needs, information should be derived from both users and end-users to enable optimal outcomes. A Match project has identified this lack of consultation .¹²⁰ See also [Appendix 13](#). MATCH Deliverable 6.

Craven et al notes that MD manufacturers operate within a tight regulatory environment (e.g. from EU Medical Device Directives) that requires much user consideration during the product lifetime including both development and deployment phases.³³ For example:

- *Design controls: as part of Good Manufacturing Process, including design inputs from users and validation of fitness-for-purpose.*
- *Observation studies: pre-trial assessment of an innovational investigative device.*
- *Pre-market approval or notification: clinical trials as evidence of safety and effectiveness and adherence to packaging and labelling requirements.*
- *Post-market surveillance. e.g. Adverse Incident reporting via the Medicines and Products Regulatory Agency (MHRA) in the UK, or the MD Reporting MDR) via the FDA in the USA.*
- *Procedures for maintenance, reuse and disposal of devices.*

However this MATCH sponsored study also noted³³ the

- *market push being the main driver rather than customer pull, so that user needs are not prioritised as the central principle;*
- *need for confidentiality resulting in early assessment iterations being conducted in-house e.g. on employees;*
- *serendipitous methods by which users are found, e.g. 'trying out' initial design ideas on acquaintances who are not the intended age group for the innovation;*
- *use of an advisory panel of clinicians (e.g. specialist physicians), that do not include the front line users of the device, (e.g. ward nurses) or hospital administrators;*
- *difficulty in pinning down expert opinions, suggesting a lack of skills in this area;*

- *devices that worked well in the hospital lab setting but are not ergonomic in the clinician's work space, or not well suited to the busy clinical environment;*
- *manufacturers having to preempt user requirements in the context of changing work practices, e.g. increasing use of out-reach teams (who would be involved in responding to alerts generated from monitoring devices for example); and*
- *manufacturers clearly identifying the need for reducing time-to-market and lower costs, but highlighting help with complex regulations and conducting clinical trial as priorities rather than improving approaches to user needs, i.e. they are not explicitly asking for guidance in human factors.*

Many of the issues raised in these points resonate with the author and have been recognised as difficulties in the development process that need to be addressed.

So how can a NZ MD developer be provided with guidance about avoiding these defects of process and what initiatives exist in NZ to support them?

6.9 Helpful Agencies & Government Initiatives

The Knowledge Economy initiative was promulgated by the government in 1999. There was a great deal of discussion around issues of education, tax, research, culture and how to stimulate innovation.¹²¹ Some growth has occurred in 'knowledge' based exports. An example is the export of customised computer software, computer consultancy services, and computer royalties that have grown steadily since 1997.¹²² However despite talk-fests such as the "Knowledge Wave" conferences earlier this decade and continuing rhetoric from politicians, NZ continues to rely on an commodity economy with none of the necessary initiatives introduced to foster hi-tech industry. International sales of manufactured goods also provides wealth – we cannot rely only on the development and exporting of services and commodities, especially commodities that are subject to wide variation in returns, due to supply and demand pressures and increasingly issues surrounding sustainability.

As the Foundation for Research Science & Technology [FRST] states: 'the manufacturing sector is fragmented, appears to have a low RS&T intensity, (although non-R&D innovation may be relatively more important due to New Zealand's distance from markets) and publicly funded research is seen as being of little relevance.'¹²³

FRST has been very supportive of R&D in industry; providing a range of funding programmes and their funding application and reporting structures are manageable and support innovation.¹²⁴

The NZ Trade & Enterprise, [NZTE] Enterprise and Business Development Grants are directed at supporting management and marketing. Their forms are complex, intrusive and the opportunity cost to complete them comprehensively, makes an application for the under \$5000 grant a marginal exercise.

A number of regional programmes support industry. The Greater Wellington Industry Development Centre [GWIDC] is an example.¹²⁵ The IDC was intended to work as a facilitator to overcome restraints to co-operation between industries, but their funding is totally inadequate and they have no long term strategic plan. Instead 'Wellington Industry' continues to build up constraints on their own by not being open towards new methods and offers of support. Many lack the management skills and vision to maximise the export potential for their business.

For long term strategic planning, a NZ MD industry requires initiatives from Govt that are not subject to political expediency and probably disconnected from Government Ministries. It is clear from the different modus operandi, that FRST takes a far less bureaucratic approach to applications and reporting than NZTE. In an increasingly over regulated business environment, there is a reluctance on the part of manufacturers/developers to involve yet another Govt. dept, especially if they have an influence on how they operate their business.

6.10 A Model for MD Development in NZ

From the foregoing it will be apparent that there are a number of critical areas where industry assistance is required if a MD development industry is to flourish in NZ. They include

- specialised manufacturing, materials and component procurement;
- access to Users/End-users;
- MD marketing;
- compliance and regulatory conformity; and
- a MD development structure, including access to affordable technology/specialist advice.

6.10.1 Specialised Manufacturing

NZ must also move towards tool-less manufacturing and direct/rapid manufacturing in production materials. These developments are of particular applicability in manufacturing operations focusing on complex customised products with relatively short production runs. In effect, the type of manufacturing operations that predominate in New Zealand.¹²³

Other technologies of great benefit to MD manufacturing would be production precision investment casting using ceramics or graphite, electro-forming, ceramic components and dedicated integrated circuit design. All of these technologies need to be scaled for limited production runs, since international suppliers are simply not interested in providing the small quantities NZ industry requires, at least for the initial stages of market development.

As previously discussed access to specialised components is very difficult for NZ SME's. Overseas suppliers are more likely to supply an established regional institution.

6.10.2 Access to Users/End-Users

The Match Group reviewed the literature of methodologies for medical device evaluation from three distinct areas: healthcare, social science and engineering and ergonomics, as the first stage in a programme of research aimed at encouraging design for user requirements and producing guidance to industry on how to embed such methods in device development. In the Executive summary, Deliverable 6C they concluded: ¹²⁶

The majority of the literature identified in this review was concerned with improving product usability.

Although usability is an important factor due to its association with medical error, the user requirements of medical device can be seen as a much wider issue than just usability and adopting an approach such as user-centred design in isolation may not be sufficient to produce a device that truly meets the requirements of all of its users.

The literature in this review mainly concentrated on product design and development with little attention paid to including users at the concept stage. In order to obtain needs-driven devices it is important that users are embedded from the very beginning of the device cycle before the design brief for a new device has been created.'

See also [Appendix 13](#). MATCH Deliverable 6. Methods To Capture User Perspectives in the Medical Device Technology Life Cycle: A Review of the Literature In Health Care, Social Science, and Engineering & Ergonomics.

6.10.3 Methods of Eliciting User Perspectives and Requirements in MD Development.

In Match Deliverable 19, Methodological Issues for the Investigation of Methods to Elicit User Perspectives and Requirements in Medical Device Development were investigated:

6.10.4 Summary of Key Issues, Findings and Conclusions ¹²⁶

Quote:

- *A comprehensive approach to the subject of medical devices and their users is necessary due to the inherently diverse nature of medical devices and users.*
- *Different disciplines apply the labels of user and end-user differently. From the engineering and ergonomics literature the user was generally regarded to be the end-user i.e. the person who will ultimately use the product. From the healthcare literature end-users were predominantly perceived to be clinicians rather than patients. In the social science literature, in addition to a focus on clinicians, multiple users were identified, including purchasers. Overall there is a significant need to clarify who the users are in relation to particular devices and the context of device use, which constitutes a core component of the areas for methodological review.*
- *End-user involvement in medical device development from the Healthcare and social science literature was mainly found in the post-market surveillance stage. In the engineering and ergonomics literature end-user involvement was predominantly approached through user-centred design concepts. The methods identified were in the main found in the product design and development stages after the design brief had been put together. Overall there was strong endorsement of the need for multiple methods to accommodate the myriad of end-users identified. A combination of methods is indicated, incorporating both subjective and objective methods.*
- *Generic methods and tools provide limited information on device performance: rather they appear to address general issues of health and wellbeing. The generic approaches to measurement illustrate the difficulties of trying to evaluate outcomes amidst the complexity of the healthcare arena and are further areas for review.*
- *Early involvement of users in the design process may reduce the problems associated with ineffective, dangerous and discarded devices before they are marketed, which also has cost implications for industry. In addition the need for feed-back mechanisms for identifying device errors and the need for device decommissioning was raised.*
- *The cost implications included access to users, finance and manpower for the adoption of user-centred designs by industry. Financial and time resources can impact on a company's ability to embed users and end-users in their design and manufacturing processes as well as in carrying out clinical evaluations. Other factors were implied, though not clearly defined, indicating a*

further area for substantive research inquiry, for example, gaining access to users through ethical and research governance processes, particularly when working with vulnerable populations.

6.11 MD Marketing

Most manufacturers fail to market MD's appropriately, resulting in lost sales potential. Any marketing programme must also be integrated with post-market surveillance.

SME's in NZ cannot justify a full time marketing employee and the ability to market internationally through the an Internet website using CRM software must be leveraged. Moreover the developer should be able to access a division of the development structure proposed below, a service centre to create and maintain on a monthly basis, a marketing programme owned by the business, thereby creating assets and a knowledge base for future developments.

6.12 Compliance & Regulatory Conformity

As discussed in Chpt 4, it is possible to develop a product related QMS that will meet the standards necessary for conformity using generic templates, supplemented by some specialist advice about current international standards.

Perhaps this could be offered by Standards NZ as an extension of their services; they already monitor international standards and would be in the most favourable position to advise the industry about conformity protocols. They might provide this as a service under contract to the service organisation.

6.13 A MD Development Structure

The Virtual Organisation structure discussed above in Cl 6.8 could be extended and publically funded to operate as a mentoring service for the development of MD's. Members of the 'hub' selected for their expertise, may meet on an 'ad hoc' basis between regular meetings, according to demand, to meet sponsors wishing to present their proposal. There would need to be some formality in this process:

- Applicants with an idea must present their proposals in an ordered construct or format, using an outline template. The proposal to include drawings/sketches, descriptions, aims and objectives for the device, proposed market, price they would be prepared to pay for the device, etc.

Following the introduction of a new proposal a feasibility study may be elicited by the hub, however they may decline to be further involved or endorse the proposal at different levels, for example – feasible but

- conditional research must be undertaken to allow a more considered review. This research would probably be undertaken by the sponsor and presented in a form acceptable to the hub; or
- proof of a market is required; and
- would be considered subject to additional resources being available. These may be accessed from off shore or elsewhere in NZ, etc.

Once the 'hub' has endorsed the project, the next stage is a 'proof of concept'. As innovative technology may be involved, it may be necessary to determine that a number of discrete elements must harmonise to produce the desired output. An example might be to determine that a physical process or phenomenon can be harnessed, measured or controlled.

From the 'proof of concept' stage, the proposal might progress into project planning. See [Chpt 4.4.1 The MD R&D Process](#).

The 'hub' may direct the applicant to an organisation specializing in a particular project planning technology, or until the project matures, it may be necessary for an appointee of the 'hub' to continue to play an active role in 'brokering' or facilitating the process by accessing a range of resources. Generally the sponsor will want to be closely involved in all aspects of the process of realising their 'dreams', however they will need to ultimately relinquish control to a manufacturer/developer. The 'hub' may assist in brokering a relationship with a manufacturer to manage the project. They may also advise about funding and continue to assist with expert advice. In due course the experience gained by manufacturers from complex project developments, will create a pool of expertise that will rely less on advice from the virtual organisation.

6.14 The Wellington Institute of Technology [WIT]

An opportunity exists for a new independent organisation to be created, providing the technology infrastructure for MD development. It should be vested in a Foundation or Trust to operate as an Institute, independently of educational policy and operating on a not for profit business model, with new technologies substantially developed at government expense, perhaps using Public Good Science and Technology and New Economy Research Funds.

The **WIT**^T would become the focus of advanced technical training, for engineering and design in association with the existing institutions of Wellington, including WELTEC, IRL, Massey School of Design and the Victoria University, Faculty of Health Engineering and Science.

T The name to include Wellington would almost certainly be politically unacceptable – could it be the Aotearoa Institute?

The Institute would develop a high technology advisory service with manufacturing capacity for any technology required for a specific development, provided that it could be leveraged for new industry and was not already available in NZ. The centre should be fully staffed to support industry throughout NZ and offering additional services including information and library facilities, marketing, compliance, intellectual property and contract law. Supporting manufacturing as it's primary role would ensure that commercial imperatives were acknowledged and as a multidisciplinary institution, the facility could support hi-tech industries of any type, not just the MD industry. A logical extension of the function of the WIT would be to involve social sciences, healthcare and health economics to provide a centre of user, end-user research.

Precedents for this structure exist with the Schools of Medicine and their association with tertiary training hospitals; students would accredited to the Institute for internships and post-graduate research.

A very similar NZ based structure to that proposed, is HERA (NZ Heavy Engineering Research Association).¹²⁷ This not-for profit research association was formed in 1978 through an initiative of the New Zealand heavy engineering industry. The formation was encouraged by government policy of the day supporting the creation of industry research associations by providing a legally binding funding basis via levies on products used by the respective industries. In the first years of HERA's operation, strong industry development needs were identified around the common fabrication technology "welding" and in order to fund those activities a new levy schedule on welding consumables was introduced in the HERA Act's first amendment in 1986.¹²⁷

HERA has continued to flourish from that base of welding and heavy structural engineering technology to forge close links with many other industry groupings including:

- Steel Construction NZ (SCNZ).
- Stainless Steel Development Association (NZSSDA).
- Steel Framed Housing (NASH).
- Composite Structural Assembly(CSA).

Close associations also exist with:

- Casting Technology New Zealand (CTNZ).
- New Zealand Engineering Federation (NZEF).

Additionally, HERA was instrumental in the establishment of the:

- Light Alloys Manufacturing – NZ (LAM-NZ) research initiative, which has a 5 year time frame to establish themselves as a stable long-term metals sector interest group.

Clearly funding by levies would not be an option for the proposed WIT, however the base funding could evolve over time from a variety of income streams from industry credits and fees, educational fees, contestable research funds, etc. As an example, in the 2005/2006 financial year HERA's income was about \$2.6 million. While the levy is a considerable proportion of the income (26%), the self generated income of 46% is substantial and demonstrates a good use of the organisation's resources by its members - see Figure 47.¹²⁷

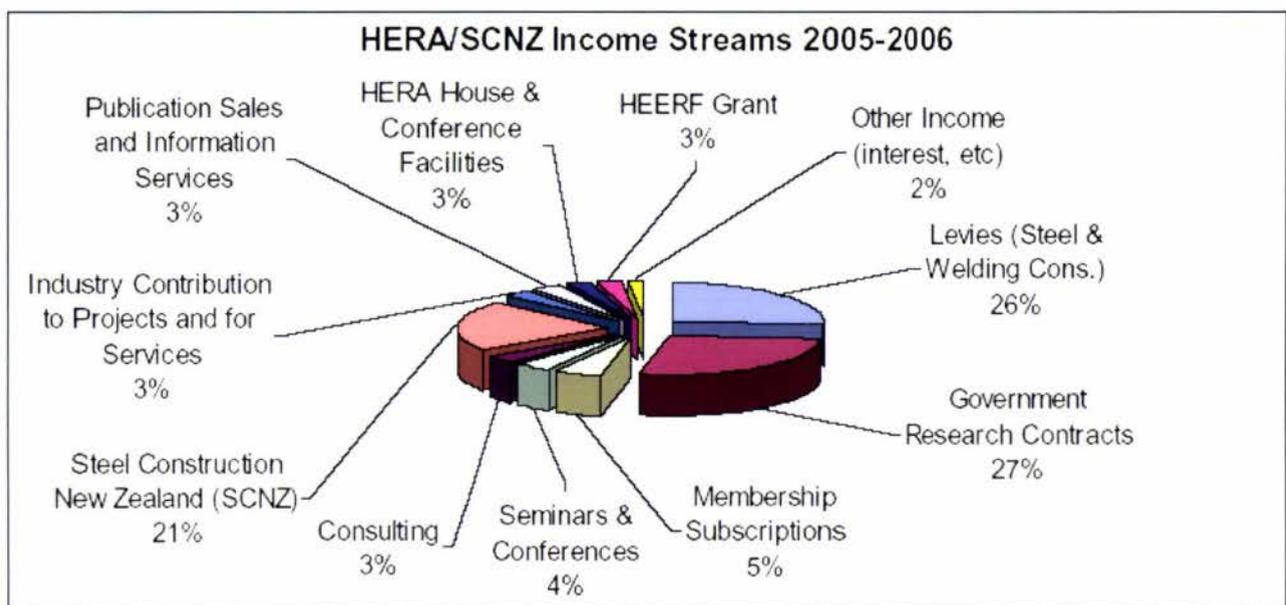


Figure 47. HERA/SCNZ Income Streams in 2005/2006

The government funded research contract contribution (mainly FRST contracts) is 27%, however this is relatively small compared to CRIs or universities. Figure 48 below shows the development of the different income streams and the HERA staff developments from its inception in 1978.¹²⁸

The HERA Executive has recognised that in order to service the future needs of it's members and also be successful in competing for government research funds, the base of the metals industry needs to be widened to provide overarching R&D and service capabilities via research levies from an alternate vehicle. This would also leverage increased industry research via the contestable route.

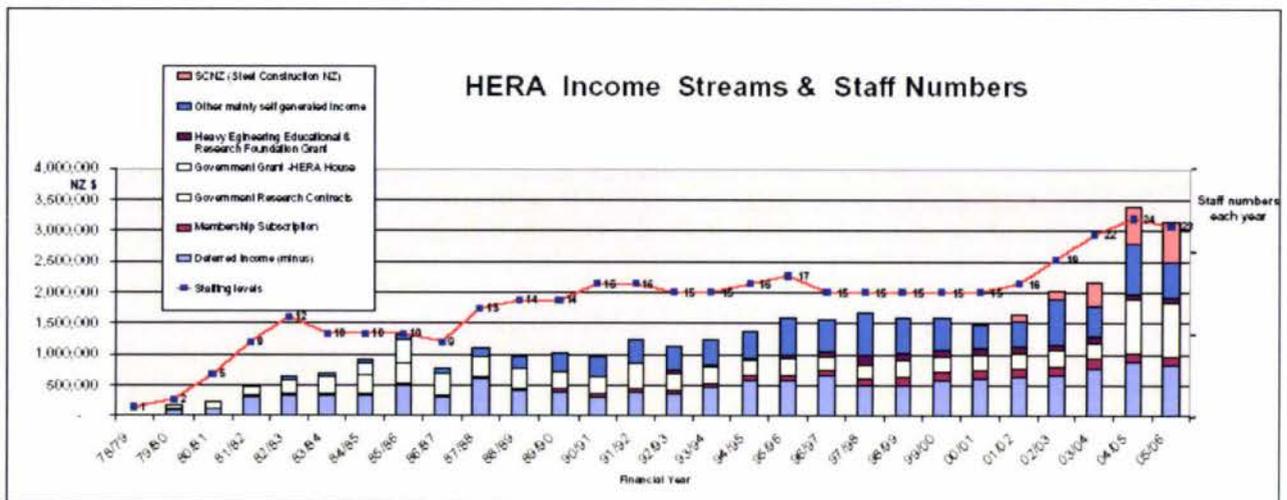


Figure 48. HERA Income & Staff Development 128

However, HERA also needs to support the different metals industry market development needs. In the process of their annual strategic review and in conjunction with a long planned HERA Levy Act Amendment, the concept was developed of creating jointly with sector industry sector groups, an overarching Metals Institute of New Zealand (MINZ).

By using the HERA Levy Act Amendment as the vehicle, a stable base funding could be achieved for the sector groups involved and MINZ itself.

Clearly there are parallels to the proposal to create MINZ with the WIT; one could foresee that the technologies developed by its sector groups such as the CTNZ & LAM-NZ, would have great benefit for the MD industry, especially if focussed by immediate applications. WIT might build a close relationship with the MINZ to co-operate and prevent duplication in R&D.

A world leading example of such an institution is the Massachusetts Institute of Technology [MIT] and while clearly NZ could not aspire to anything like this example, a modest but very functional facility is feasible with goodwill and some forward thinking by the Government.

There would be enormous obstacles to be overcome with probable changes in NZ law and government regulations. The Tertiary Education Commission [TEC] and Tertiary Institutional Governance Boards would no doubt find every possible reason to criticise the idea. It would need a nationally recognised champion, an individual with vision, drive and initiative to advance the structure.

The rewards for Wellington and NZ would be far reaching and an ultimately a significant driver for the

national economy. It would be actually doing something – not just talking about it.

NZ's brightest graduates might be encouraged to remain in NZ to contribute to this centre of excellence. The stimulus to advanced education, technical and trade training would be enormous, with the focus on MD's providing challenges not to be found in traditional product development methodologies.

7. Conclusions

7.1 The Future for MD Manufacturing in NZ

The international demand for MD's can only increase as there is also a global transition from traditional, across to Quality of Life [QOL] ¹²⁸ and Quality of Service [QOS] ^{129,130} healthcare. This means that internationally the MD industry will undergo transformation as new pressures come to bear by population's expecting full life-cycle care and Governments extracting value from health expenditure.

Globally governments are struggling to manage healthcare budgets, however disease profiles differ between the poorer and more affluent countries.

In third world countries, poor sanitation, inadequate vaccination programmes & malnutrition shorten life expectancy, so to a large extent chronic conditions of old age are less prevalent because people do not live long enough to develop them. The emphasis is mostly on public health programmes to provide fresh water and mosquito nets, improve food production, distribution and storage, vaccination, etc. So MD's in third world countries are relatively less important in budget planning.

New Zealand is typical of affluent countries where health expenditure is steadily rising. However this does not necessarily correlate with a healthier population! ¹³¹ See Figure 49

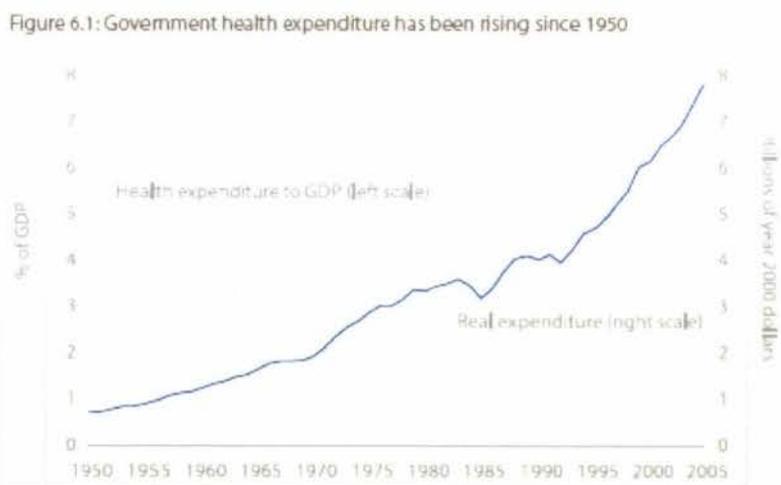


Figure 49. NZ Government Health Expenditure

In any particular year, health-care costs of individuals in affluent countries increase with their age. In addition, the developed and developing worlds, are undergoing population ageing. These two facts have led

many to conclude that population ageing will inexorably lead to large and rapid increases in health expenditure. However international research is equivocal about the linkage. More fundamentally, the focus on age structure may be misplaced, because underlying health status, rather than age, may be the real determinant of the demand for health care.¹³¹

What is clear however is that the congruent medical conditions including diabetes, heart disease and stroke associated with obesity and lack of exercise, have a significant effect on morbidity in developed nations.¹³²

MD's will be required in increasing numbers for diagnosis and treatment of the unhealthy, while assistive devices will be needed for patient lifting and mobility. Other conditions more prevalent in the aged such as CORD, osteo arthritis and sensory impairment, increase dependance on assistive devices for life support or to ameliorate handicaps such as deafness and blindness.

In the context of international MD developments, NZ starts from a very low MD industry base, there being only a few companies fully manufacturing; most are importing and marketing. However NZ is positioned with a unique European demographic, low regulatory entry and barriers for product development. Many countries would see us as a good testing ground; however sustaining an industry is another issue all together!

As discussed, there are problems of access to overseas sources of specialised components and with NZ manufacturing, including poor quality and unreliable delivery. These are issues that are enormously frustrating for the NZ MD developer and very expensive because of lost opportunity and direct costs related to remakes.

7.2 MD vs. Traditional PD Methodologies

The special features of MD development were examined and from studies carried out by the MATCH Group and guidance documents from the FDA and European regulatory bodies, in particular the GHTF, it was clear that users and end-users must be involved at every stage of the specification and development. This perspective provides a far greater assurance that the MD will function as anticipated and that the final outcome will be reliable and safe.

NZ manufacturers are not generally familiar with the field of human factors except perhaps in passing, with references to workplace furniture, however the FDA consistently stresses the importance of ergonomics and rigorous design controls. Design controls are a component of a comprehensive and consistently maintained quality system that covers the life of a device. The assurance process is a total systems approach that extends from the development of device requirements through design, production, distribution, use, maintenance, and eventually, obsolescence. Design control begins with development and approval of design inputs, and

includes the design of a device and the associated manufacturing processes.¹³⁴

Design Control hinges on a comprehensive and maintained QMS. The author's example uses templates that can be modified to suit the business structure. With recent software developments it is possible to integrate manufacturing and financials with customer resources, thereby facilitating resource and compliance management. The use of Servage, Groove or similar internet based programmes enables flexibility in the structure of 'virtual organisations' convened on an 'ad hoc' basis for a particular project or development. Members of the design team may be involved on the basis of any one of a number of beneficial business arrangements, but they are largely able to operate from their own work site with minimal disruption to their normal routine via the internet. This leaves them free to continue with their existing commitments and responsibilities. It therefore becomes easier to attract and involve the most beneficial expertise for a project.

Most manufacturers contemplating the development of a MD in NZ will be unfamiliar with, or ill equipped to manage QMS's and compliance, let alone international marketing, post-market surveillance and tracking issues. Some expert guidance will be necessary to ensure that all compliance issues are addressed as the procedures are many and complex. The Case Study illustrated this complexity and the difficulties of complying and managing the process without overwhelming the company.

However it is particularly with low classification assistive devices, that NZ could gain experience in managing developments within the constraints of a QMS, compliance regimen and manufacturing technologies and skill base, to be able to venture into more advanced technology developments in the future. To encourage this process however, the Government must provide the framework to broker innovation, not to subsidise industry, but to support it with a specialised infra-structure.

At present there is little if any infra-structural support from Government and academic and research organisations to facilitate the process and what is available is unaffordable by individual ME's.

In short, it is unlikely that any development of advanced technology industry for manufacturing MD's in NZ will eventuate without a radical shift in government policy. There is a great deal of talk about Better by Design, management, efficiency, etc, etc, but the key policies are those that promote the production of highly technological MD's that are safe, compliant, usable and effectively marketed internationally. It is about facilitating the transfer of knowledge, developing skills and educating professionals, establishing new manufacturing technologies currently unavailable in NZ and adopting a culture that supercedes traditional product development methodologies.

7.3 A NZ Model

The aim of this thesis was to develop a systematic management model to facilitate medical device manufacturing in NZ and demonstrate how compliance in major international markets could be achieved.

To the extent that the Case Study illustrated such a model that would indeed guide the medical device manufacturer, why would they bother traditional products are so much easier to design, manufacture and market? Drawings can be on the back of an envelope, management by an email communication or a telephone call and there is no regulatory authority ready to hang you out to dry!

The differences between MD and a traditional product development have been highlighted in detail and if some of the solutions and recommendations were adopted the rewards for the NZ economy would be very significant. We could become niche players in the international MD market. The technology spin-offs could be leveraged into other industries such as control instrumentation for yachting, industrial processing and primary industry. The Knowledge Economy would mean something [other than in the field of IT]; it would provide a focus for our young scientists, technologists, ergonomists, social engineers, etc, and stem the drift off shore to progressive economies.

A structure was suggested to achieve these goals – the WIT. It is a possible model; it is a concept that would require a great deal of discussion and no doubt changes in the laws and regulations of NZ. But if we do not widen our view of the world and develop a manufacturing potential to cushion the economy, we are doomed to continuing balance of payments deficits, stagnation, depreciation of our standard of living and to mediocrity.

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APPENDICES

Appendix 1 – Definition of a Medical Device

From 93/42/EEC - Definition of a Medical Device ²

2. For the purposes of this Directive, the following definitions shall apply:

(a) '**medical device**' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) '**accessory**' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

(c) '**device used for in vitro diagnosis**' means any device which is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of samples derived from the human body with a view to providing information on the physiological state, state of health or disease, or congenital abnormality thereof;

(d) '**custom-made device**' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The above mentioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices;

(e) '**device intended for clinical investigation**' means any device intended for use by a duly qualified

medical practitioner when conducting investigations as referred to in Section 2.1 of Annex X in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

(f) '**manufacturer**' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

(g) '**intended purpose**' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

(h) '**placing on the market**' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(i) '**putting into service**' means the stage at which a device is ready for use on the Community market for the first time for its intended purpose.

Appendix 2 – WEEE & RoHS Directives ^{97,98}

Extracted from documents listed below.

As of 01 July 2006, the 25 EU Member States will feel the significant effects of two new European directives with regard to electrical and electronic equipment, being the WEEE directive 2002/96/EC (Directive on Waste Electrical and Electronic Equipment) and the RoHS directive 2002/95/EC (Directive on the Restriction of the Use of Certain Hazardous Substances).

The objectives of the WEEE and RoHS directives are to stimulate innovative and constructive solutions that minimise the use of hazardous substances in electrical and electronic equipment.

- In terms of scope, the WEEE directive imposes restrictions on the use of hazardous substances during the manufacture and recycling of electrical and electronic equipment.
- In addition to recycling electrical and electronic equipment, reuse and other forms of a second life-cycle for electrical and electronic components are stimulated.
- A producer who puts electrical and/or electronic equipment on the European market after 31 June 2006 must guarantee that his equipment and the processing thereof (reuse and recycling) meet the requirements of the WEEE directive.
- From 01 July 2006, the RoHS directive prohibits the use in Europe of specific substances in electric and electronic equipment. These banned substances are lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated biphenyl ethers (PBDE).

The WEEE directive 2002/96/EC / 2003/108/EC ⁹⁸

The WEEE directive applies to electric and electronic equipment that meets the following three criteria:

- Equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields.
- Equipment falling under the categories set out in Annex IA and more specifically Annex IB

to Directive 2002/96/EC (WEEE).

- Equipment designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current.

The producer is only required to act in accordance with the mandatory requirements of the WEEE directive if all three criteria above apply to electrical and/or electronic equipment in a complete state.

- The producer must demonstrate the compliance of his electric and/or electronic equipment with the WEEE directive by means of the three markings below.
- Symbol of Annex IV to the WEEE directive, being the crossed-out wheelee bin.
- Identification of the enterprise with European responsibility.
- Indication of the year on which the equipment was placed on the European market.

The RoHS Directive 2002/95/EC

The RoHS directive concerns electric and electronic equipment falling under the categories set out in Annex IA and more specifically Annex IB to Directive 2002/96/EC (WEEE), being categories 1, 2, 3, 4, 5, 6, 7 and 10. This electrical and electronic equipment may not contain substances such as lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

Appendix 3 – Recent changes to ISO standards ^U

| Designation | Title | Superseded by.. | Stage date: |
|------------------------|---|--|-------------------------|
| EN ISO 14971-1:1998 | Medical devices - Application of risk management to medical devices | EN ISO 14971:2007 | 28 th Feb 07 |
| EN1441:1997 | Medical devices - Risk analysis | EN ISO 14971:2007 | 28 th Feb 07 |
| EN60601-1-4: | Medical electrical equipment Part1: General requirements for safety 4: Collateral Standard: Programmable electrical medical systems | EN ISO 14971:2007 | 28 th Feb 07 |
| EN 46001:1996 | | Withdrawn 1/3/04 | |
| EN 46002:1996 | | Withdrawn 1/3/04 | |
| AS/NZS ISO 9000.1:1994 | Quality management and quality assurance - Standards Guidelines for selection and use | AS/NZS ISO 9000:2000 | |
| AS/NZS ISO 9000:2000 | | AS/NZS ISO 9000:2006 Incorporates changes accepted in the ISO draft Amendment ISO/DAM 9000:2004 | |
| AS/NZS ISO 9001.2:1998 | Quality management and quality assurance Standards - Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003 | ????? | |
| AS/NZS ISO 9001:1994 | Quality systems - Model for quality assurance in design, development, production, installation and servicing | *AS/NZS ISO 9001: 2000 | |
| AS/NZS ISO 9002:1994 | Quality systems - Model for quality assurance in production, installation and servicing | *AS/NZS ISO 9001: 2000 | |
| AS/NZS ISO 9003:1994 | Quality systems - Model for quality assurance in final assurance in final inspection and test | *AS/NZS ISO 9001: 2000 | |

^U Table developed by Author.

| Designation | Title | Superseded by.. | Stage date: |
|---------------------------|---|------------------------|--------------------|
| AS/NZS ISO 9004.1:1994 | Quality management and quality system elements - Guidelines | AS/NZS ISO 9004: 2000 | |

Bibliography for ISO 13485:2003(E)

| Designation | Title | Superseded by.. | Stage date: |
|-------------------------|--|------------------------|--------------------|
| AS/NZS ISO 9001:2000 | Quality management systems - Requirements | | |
| ISO 10012 | Measurement management systems- Requirements for measurement processes and measuring equipment | | |
| ISO 11134:1994 | Sterilization of health care products- Requirements for validation and routine control - Industrial moist heat sterilization | | |
| ISO 11135:1994 | Medical devices- Validation and routine control of ethylene oxide sterilization (Corrigendum 1 published 1994) | | |
| ISO 11137:1995 | Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization (Corrigendum 1 published 1995; Amendment 1 published 2001) | | |
| ISO 13641:2002 | Elimination or reduction of risk of infection related to in vitro diagnostic medical devices | | |
| ISO 13683:1997 | Sterilization of health care products - Requirement for validation and routine control of moist heat sterilization in health care facilities | | |
| ISO 14155-1:2003 | Clinical investigation of medical devices for human subjects - Part 1: General requirements | | |
| ISO 14155-2:2003 | Clinical investigation of medical devices for human subjects- Part 2: Clinical investigation plans | | |

| Designation | Title | <i>Superseded by..</i> | <i>Stage date:</i> |
|-----------------------------|---|------------------------|--------------------|
| ISO 14160:1998 | Sterilization of medical devices - Validation and routine control of sterilization of single-use medical devices incorporating materials of animal origin by liquid chemical sterilants | | |
| ISO 14937:2000 | Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development validation and routine control of a sterilizing agent | | |
| ISO/TR 14969:- ¹ | Medical devices- Quality management systems - Guidance on the application of ISO 13485:2000 | | |
| ISO 14971:2000 | Medical devices - Application of risk management to medical devices | | |
| ISO 19011:2002 | Guidelines for Quality and/or Environmental Management Systems Auditing | | |
| | Global Harmonization Task Force (GHTF) - Study Group 1 (SG1) Document No.N029R11 dated 2 Feb. 2002 | | |

¹ To be published.

References to Auditing Standards

| Designation | Title | Superseded by.. | Stage date: |
|------------------------|---|------------------------|--------------------|
| GHTE/SG4/N28R2 | Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements (1999) | | |
| GHTE/SG4/N30R18 | Guidelines for Regulatory Auditing of Quality management systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy (final document 16 February 2006) | | |
| GHTE/SG2/N36R7 | Manufacturer's Trend Reporting of Adverse Events | | |
| US FDA 21 CFR Part 820 | Quality System Regulation (October 7, 1996, Federal Register 61 FR 52602) | | |
| ISO 9000:2005 | Quality Management Systems - Fundamentals and Vocabulary | | |
| ISO 13485:2003 | Medical devices - Quality Management Systems - Requirements for Regulatory Purposes | | |
| ISO 19011:2002 | Guideline for Quality and/or Environmental Management Systems Auditing | | |

Appendix 4 – SOP 17 – Quality Records ^V

| Revision History | | | | | |
|------------------|-----------|-----------|---|--------------|---|
| Change Note No. | Old Issue | New Issue | Description of Change | Release Date | Approval Signature |
| CN 001 | N/A | 1 | New Release | | |
| CN 0103 | 1 | 2 | Superseded references and inappropriate wording | 14/7/07 |  |

1.0 Scope:

This document establishes the requirements for the control, storage and retention of records.

2.0 Applicable Documents:

ISO 13485:2003(E) Quality Systems-Medical Devices-Particular Requirements for the Application of ISO 9001:2000

ISO 9001:2000 Quality Systems – Requirements. European Communities Medical Devices Directive (MDD) 93/42/EEC

3.0 Responsibilities:

The Managing Director [MD] will be responsible for ensuring that all quality records are readily accessible and retrievable.

4.0 Procedures:

4.1 Each record will be legible and will be stored in a form and a location to minimize deterioration and to ensure easy retrieval.

4.2 All documents pertaining to a specific product or procedures associated with its manufacture will be retained for at least five (5) years after the last product has been manufactured.

4.3 All documents forming part of the Quality Management System, and those documents and records referred to within it, are considered to be quality records.

4.4 One copy of all obsolete documents will be retained as a quality record.

5.0 Record Retention

This SOP will be retained in accordance with the requirements of this SOP.

^V Document developed for author's company

Appendix 5 – IEC 60601-X Standards ^{W 135}

As noted in the Footnote below the following has been updated, appended and paraphrased from the article by Eisner L. et al.

A5.1 The IEC 60601 Standard

The IEC 60601–1 standard, Medical Electrical Equipment – Part 1: General Requirements for Safety, is the cornerstone document addressing many of the risks associated with electrical medical equipment.

Electromedical products are defined in IEC 60601–1 Subclause 2.2.15 as

'equipment, provided with not more than one connection to a particular supply mains and intended to diagnose, treat, or monitor the patient under medical supervision and which makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects such energy transfer to or from the patient'.

Examples of products fitting this definition include battery-operated thermometers, MRI and gamma imaging systems, endoscopic cameras, infusion pumps, and many others. Accessories used with such equipment can also fall under this standard.

The IEC 60601 standards series consists of four distinct parts. The EC 60601–1 base standard is the core of the series and a part of the 60601–1 grouping (base and collateral). The 60601–2 grouping includes particular device-specific standards, and the 60601–3 grouping includes performance and device-specific standards. ¹³⁴

A5.2 Base Standard

IEC 60601-1 covers all the general requirements for electrical medical (or electromedical) products.

A5.3 Collateral Standards

Standards numbered IEC 60601–1–x contain horizontal issues that may deal with many different types of medical devices. IEC 60601–1–2 is an example of a collateral standard, and it encompasses electromagnetic compatibility (EMC) issues of electrical medical devices. A standard on the horizon in this category is IEC 60601-1-6, which deals with human factors (usability) issues.

^W The article by Eisner, L. Brown, R.M. & Modi, D “A Primer for IEC 60601-1” MDDI Sept 2003 ¹³⁴ provides an excellent framework for this appendix. The appendix represents a paraphrasing of sections of the article with revisions to correct changes to standards and protocols that have occurred since the publishing date of 2003.

A5.4 Particular Standards

Standards numbered IEC 60601-2-x lay out requirements for a specific type of medical device.

IEC 60601-2-2 is the particular standard for high-frequency surgical devices. Particular standards can amend, modify, and/or supersede part of the requirements specified in IEC 60601-1.

A5.5 Performance Standards

Standards numbered IEC 60601-3-x lay out performance requirements for specific types of devices. IEC 60601-3-1, for example, contains "essential requirements for the performance of transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment."

A5.6 IEC 60601 and National Standards

As illustrated in Table 1 the base standard IEC 60601-1 has been adopted as a national standard in most major countries.

| COUNTRY | IEC 60601-1 ADOPTED AS: |
|-----------------------|---|
| United States | ANSI/ UL 2601-1 (U.S. national deviations) |
| Canada | CAN/CSA C22.2 No. 601.1(Canadian national deviations) |
| European Union | EN 60601-1 (identical to IEC 60601-1); in UK, BS EN 60601-1 |
| Japan | JIS T0601-1 (Japanese national deviations) |
| Australia/New Zealand | AS/NZ 3200.1 (Australian and New Zealand national deviations) |

Table 1 IEC 60601-1 national standards

Note that in the United States, UL 2601-1 has been changed to UL 60601-1, 1st edition, titled Medical Electrical Equipment, Part 1: General Requirements for Safety, published April 25, 2003. There are no changes to the requirements from UL 2601-1. There is a change in the formatting of the standard. All the U.S. deviations as well as amendments 1 and 2 of IEC 60601-1 are combined within the body of the standard.

A5.7 Other Medical Standards

Although there are other national medical standards, IEC 60601-1 is the governing standard for electrical medical products.

A5.8 Global Regulatory Importance of IEC 60601-1

Compliance with IEC 60601-1 and/or a national standard does not equal medical device approval. Compliance is step one, approval step two, and marketing step three.

The Global Harmonization Task Force,¹³⁵ established by the United States, Canada, Australia, Japan, and the European Union, gives credence to using the IEC 60601–1 standard as the model for compliance of electrical medical devices.

A5.9 United States.

The FDA recognizes IEC 60601–1 as a consensus standard with any amendments, and with specific national alterations, such as ANSI/UL 2601–1. More information regarding FDA's consensus standards can be found at their Database¹³⁶

The agency has stated that conformance with recognized consensus standards like IEC 60601-1 can provide a reasonable assurance of safety for many applicable aspects of a MD and has direct bearing on safety determinations made during FDA's premarket application reviews. The premarket application process may include: premarket notification (510(k)), investigational device exemption (IDE) application, premarket approval (PMA) application, humanitarian device exemption (HDE) application, or product development protocol (PDP).

With the use of a consensus standard, a submission can contain a declaration of conformity to that standard and eliminate the need to submit the bulk of test data for those aspects of the device addressed by said consensus standard. As a consensus standard, IEC 60601–1 also allows manufacturers of electro-medical products to use the abbreviated 510(k) paradigm where appropriate. Information on the 510(k) paradigm can be found in Appendix 13.

A5.10 European Union

The European Union (EU) in the Medical Devices Directives (MDD; 93/42/EEC; EN 60601–1 (identical to IEC 60601–1) a harmonized standard.¹³⁷ For products complying with EN 60601–1, this declaration gives a "presumption of conformity" to a large majority of the essential requirements of the directives. Meeting the essential requirements is a major step toward receiving a CE mark for a device.

A5.11 Canada

The Therapeutic Product Directorate (TPD) of Health Canada is the Canadian approval agency and recognizes CAN/CSA C22.2 No. 601.1 as the regulatory compliance standard for electrical medical devices.¹³⁸ Canada's approval system is similar to that of the EU. The major differences are the registration process, the classification system, the postmarket surveillance method, and the quality system standards used.

A5.12 Japan

The Ministry of Health, Labor and Welfare is the regulatory agency in Japan. JIS T0601-1 is recognized as the compliance standard to support registration of electro-medical products.¹³⁹ The Japanese Association for the Advancement of Medical Equipment (JAAME) is a designated agency appointed by MHLW under the Pharmaceutical Affairs Law. Evaluation data from JAAME or a foreign equivalent organization (such as Underwriters Laboratories or TUV Product Service) based on the JIS T0601-1 standard are accepted in the medical device approval process. Medical devices requiring clinical studies for approval will also have data collected on the product for three years after the product is released, per the MHLW postmarket safety assurance program.

A5.13 Australia

The Therapeutic Goods Administration (TGA), a part of the Federal Department of Health and Ageing, is the regulatory agency in Australia. Medical devices go through a premarket assessment and are assigned an AUST R number in the Australian Register of Therapeutic Goods, or ARTG. The ARTG is the computer database for therapeutic products approved for supply in or export from Australia.¹⁴⁰

Manufacturers of therapeutic goods must be licensed and their processes must be compliant with good manufacturing practices, or GMPs. Postmarket surveillance of products includes investigation of failures, laboratory testing, and monitoring for compliance with legislation.

The use of standards to support regulatory approval and registration is voluntary, but the use of IEC 60601-1 or AS/NZ 3200.1 to support the electrical safety portion of an application has been acceptable in Australia for some years. The mutual recognition agreement (MRA) between Australia and the EU is finalized. This allows the TGA to permit some EU-notified bodies to assess products and companies in light of the Australian regulations.¹¹²

A5.14 New Zealand

The NZ Medicines and Medical Devices Safety Authority (MEDSAFE) has to large extent no harmonised with Australia.¹⁴¹ NZ maintains a separate database known as Web-Assisted Notification of Devices Database. (WAND).¹¹² Otherwise the conformity processes are essentially the same as Australia.

A5.15 Other Countries

The regulatory environment is growing in Pan-Asian and South American countries. Countries are adopting regulations for medical devices, or increasing the enforcement of regulations already on the books. Most of

the countries are following the model of the GHTF. The GHTF model is similar to that of the EU, and gives importance to the recognized (international) standards for showing compliance to the essential principles of safety and performance/efficacy. Most of the countries that have established regulations (and enforce them), such as Korea, Brazil, and Argentina, recognize the IEC 60601-1 standard for showing compliance of electromedical products to the general safety requirements of the regulation.

A5.16 Structure of the Base Standard

The structure of the base IEC 60601-1 standard is hazards-specific. It provides requirements for evaluating the common hazards associated with electromedical products. Its scope is to protect both patients and users by reducing the likelihood of the following hazards.

A5.17 Electrical Shock Hazards

Reduce exposure (access to the user or the patient) to voltages exceeding 25 V ac or 60 V dc, energy hazards, and/or excessive allowable leakage currents. Provide for separation of circuits, proper grounding, and meeting the appropriate dielectric tests. Refer to section 3 of IEC 60601-1.

A5.18 Mechanical Hazards

Reduce exposure to moving parts, pinching, crushing, overtilt, expelled parts, dropping, supports breaking, and others. Refer to section 4 of IEC 60601-1.

A5.19

Radiation Hazards. Reduce the risk of x-radiation exceeding 0.5 mrd in a one-hour period at a distance of 5 cm from accessible surfaces outside the treatment zone. Refer to section 5 of IEC 60601-1. For EMC, refer to the collateral standard, IEC 60601-1-2. IEC 60601-1-2, second edition, introduces the concept of essential performance which is being incorporated into the draft third edition of IEC 60601-1. Refer to the basic concept section.

A5.20

Ignition Hazards of Flammable Anesthetics. Reduce the exposure of flammable anesthetics to static discharge, corona discharge, high-energy circuits, and restricted ventilation, among others. Refer to section 6 of IEC 60601-1. Note that flammable anesthetics are seldom used today.

A5.21

Fire and Other Hazards. Reduce the exposure to excessive temperatures, liquid spillage, pressure vessels, human errors, and other such hazards. For biological hazards (bio-compatibility), refer to the international standard ISO 10993-1. For detailed requirements on human errors, refer to the appropriate IEC 60601-2-xx standard specific to the device under test. Refer to section 7 of IEC 60601-1.

A5.22

Excessive (Energy) Output Hazard. Reduce exposure caused by inaccuracy of operating data or the accidental high setting of output. For detailed requirements on excessive output, refer to the IEC 60601-2-xx standard specific to the device under test. Refer to section 8 of IEC 60601-1.

Sections 1 and 2 of IEC 60601-1 address the general requirements for tests (such as definitions and classification) and environmental conditions (including temperature, humidity, supply voltage, and others). Section 9 identifies abnormal and fault conditions which must be evaluated. Some foreseeable failure conditions include blocked vents, locked fan rotor, and short and overload of isolation transformers. Section 10 addresses the general construction requirements for enclosure, components, and grounding (or earthing) that are not included in the other sections, yet support the requirements of those sections.

A5.23 Basic Concept

IEC 60601-1 requires that two levels of protection be employed in various areas of the product to meet the requirements of the standard. If one level of protection fails, the product would then still have another level of protection to contain any electrical shock hazards and shield patients and operators from harm.

IEC 60601-1 permits three building blocks to be used in various combinations to meet the "two levels of protection" requirement. These building blocks are insulation, protective earthing, and protective impedance. For example, a protective earth (one level of protection) used in combination with basic insulation (one level of protection) provides the two levels of protection that are required. Alternatively, a product's plastic enclosure that has reinforced insulation (considered two levels of protection) between the outside of the enclosure and its circuits again achieves two levels of protection.

IEC 60601-1 is based on the same concept as risk management. That is, to assess and control risks in the product design, manufacture, and intended use. IEC 60601-1 uses one or more of the following risk-control measures: it forces inherent safety by design, it imposes protective measures in the medical device or its

manufacturing process, or it requires instructions and/or labeling information for safety.

The draft third edition of IEC 60601–1 cites the international risk management standard ISO 14971. The third edition of IEC 60601–1 is at the committee draft for vote (CDV) level of the standards development process. The first committee draft vote (CDV-1) failed to attract a positive vote. It is hoped that a second CDV will be voted on before the end of 2003, after the September 22–October 2, meeting of Subcommittee 62A in Frankfurt, Germany.

The third edition broadens the concepts in the second edition (of basic safety) and adds requirements of essential performance to the standard. These are performance characteristics necessary to maintain residual risk (risk after protective measures are taken) within acceptable limits.

The third edition will have two types of requirements. These include requirements needing evaluation based on tests or document review—and not requiring a risk analysis, and requirements where evaluation requires the manufacturer to conduct risk analysis.

A5.24 Classification

IEC 60601–1 specifies requirements based on the product classification. The classification of the medical product must be determined first in order to proceed with the class-specific requirements of the standard. Product classification is based on different criteria in terms of safety and intended use. Classification criteria include the following.

A5.25

Protection against Electrical Shock. For devices powered by an external source, the product may be classified as Class I or II. Class I is a product that is provided with a reliable protective earth (PE), such as a complete metal enclosure, that is protectively tied to the ground pin of the three-pronged power plug. Construction is such that accessible metal parts cannot become live in the event of a single fault. Class II is a product without a PE and where double or reinforced insulation is relied upon to provide protection against electric shock. For example, a product has an external brick power supply that provides double insulation. The Class II symbol is a double-walled square, indicating the product's double insulation.

A5.26

Degree of Protection (Applied Part) against Electric Shock. This product classification deals with the definition of applied parts—those parts or circuits that deliberately come in physical contact with the patient. The classification applies to each applied part. They are classified either as type B, BF or CF, depending on

the degree of protection they offer against electric shock.

A5.27

Degree of Protection Against Ingress of Liquids. This classification deals with device construction to protect it from the entry of a liquid. It is identified by IP code as specified by IEC 60529. In most cases, other than foot switches, it is up to the manufacturer to determine the IP rating and pass the appropriate level tests.

A5.28

Use with Flammable Anesthetics. There are three classifications for products that depend on their compatibility with flammable anesthetics.

There are seven classifications based on the installation or use of the product. They are handheld, mobile, portable, transportable, stationary, permanently installed, and fixed equipment. Although some of these words seem identical in terminology, they have distinct definitions within the standard.

IEC 60601-1 also defines five modes of operation. These include continuous, short-time, intermittent, continuous operation with short-time loading, and continuous operation with intermittent loading. The most common classification of operation is continuous. The other four modes of operation limit the range in which the product is utilized, and the product is certified with those limits of use.

Appendix 6 – Directive 2002/96/EC ⁹⁷

Directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment (WEEE)

Extract paraphrased:

10 Categories of electrical and electronic equipment covered by WEEE

Directive

- Large household appliances [18 Categories] exception of large-scale stationary industrial tools) [8 Categories]
- Small household appliances [12 Categories]
- IT and telecommunications equipment [23 Categories]
- Consumer equipment [8 Categories]
- Luminaires for fluorescent lamps with the exception of luminaires in households
- Straight fluorescent lamps
- Compact fluorescent lamps
- High intensity discharge lamps, including pressure sodium lamps and metal halide lamps
- Low pressure sodium lamps
- Other lighting or equipment for the purpose of spreading or controlling light with the exception of filament bulbs
- Electrical and electronic tools (with the exception of large-scale stationary industrial tools) [8 Categories]
- Toys, leisure and sports equipment [6 Categories]
- Medical devices (with the exception of all implanted and infected products) [10 Categories]
- Monitoring and control instruments [5 Categories]
- Automatic dispensers [5 Categories]

Obligations of producers (manufacturers)

The WEEE symbol must be placed on an EEE product if the product falls in one of the 10 categories

and is placed onto the EU market after the 13th August 2005. The product is treated as "new" WEEE. Producers must provide refurbishment, treatment and reuse information for each "new" WEEE.

European Union's WEEE Directive 2002/96/EC on Waste of Electronic and Electrical Equipment obligates member states to establish and maintain a registry of producers putting electrical and electronic equipment onto the market. So far, there does not exist a centralized European registration office. WEEE producers must register in individual member states of the EEA (EU+EFTA) which are listed below:

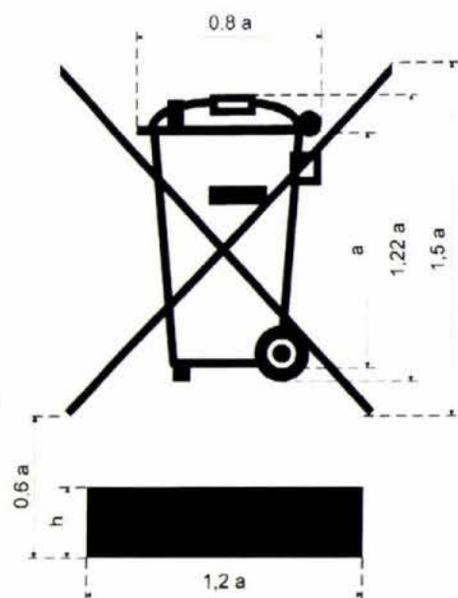
Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Estonia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, & United Kingdom (Great Britain).

Without the WEEE registration a product cannot be placed on in the EU market

- Producers will be expected to pay an annual registration fee to the appropriate Agency
- Producers, or WEEE compliance schemes acting on their behalf, will be required to report data on the amount of EEE which they put onto the market.
- Producers will be required to report this data annually to the Agencies. It will be an offence not to do so.

The WEEE symbol

The WEEE symbol, indicating separate collection for WEEE - Waste of electrical and electronic equipment, consists of the crossed-out wheeled bin, as shown below. The symbol must be printed visibly, legibly and indelibly and is required per the Article 11(2) of the WEEE Directive. It is also prescribed by European standard EN50419:2005. This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved.



Appendix 7 – Application for Certificate of Approval ⁹⁵



File:
Ent'd:
No:
Fee Received:
FOR MINISTRY USE ONLY

Application for Certificate of Approval

Application for issue of an approval for declared article under Regulation 101 of the Electricity Regulations 1997.

| | | | |
|--------------------|--------------------------|-----------|--------------------------|
| Full Business Name | <input type="text"/> | | |
| Contact Name | <input type="text"/> | | |
| Telephone | () <input type="text"/> | Facsimile | () <input type="text"/> |

| | | | |
|----------------|----------------------|----------|----------------------|
| Postal Address | <input type="text"/> | | |
| Suburb | <input type="text"/> | | |
| City | <input type="text"/> | Postcode | <input type="text"/> |
| Country | <input type="text"/> | | |

| | |
|----------------------------------|----------------------|
| Application for Declared Article | |
| Make | <input type="text"/> |
| Model(s) | <input type="text"/> |
| | <input type="text"/> |

General Description (continue on separate sheet if necessary)

| |
|----------------------|
| <input type="text"/> |
| <input type="text"/> |
| <input type="text"/> |
| <input type="text"/> |

| | |
|--|--|
| Where applicable the following items should accompany the application: <i>please indicate</i> | |
| <input type="checkbox"/> Test Report | <input type="checkbox"/> Technical description, including photos |
| <input type="checkbox"/> Sample of the article | <input type="checkbox"/> Other: <i>please specify</i> |

Please note this application is to be accompanied by the prescribed fee of \$400 (GST Inclusive).

Signature: Date / /

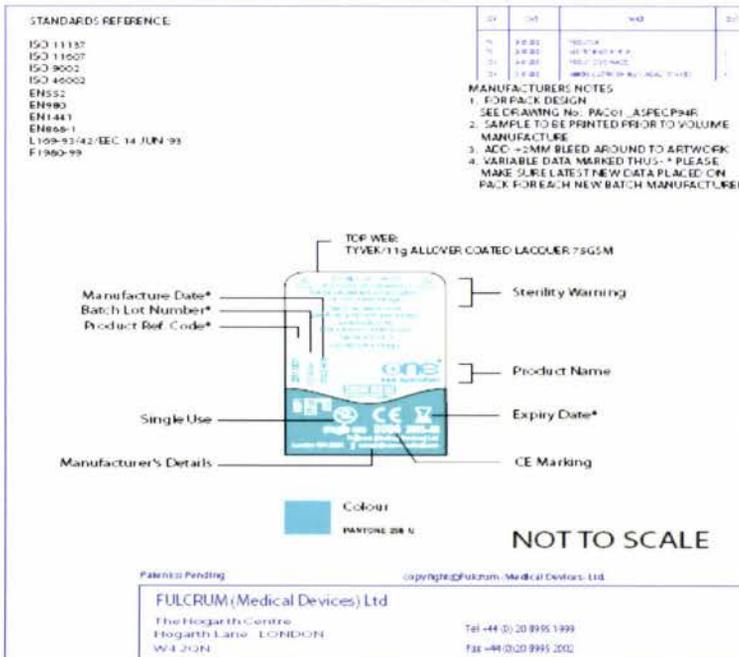
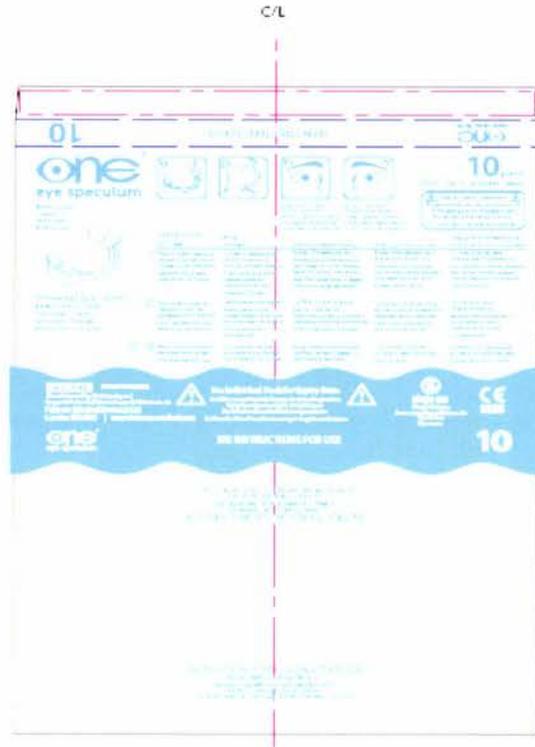
Forward to:
Operations Manager, Energy Safety Service
Ministry of Consumer Affairs
PO Box 1473, Wellington, New Zealand
620663 - ESS2/02

Appendix 8 – Examples of Compliant Labelling*

* Kindly supplied by Paul Sinding – Design Consultant

Examples of packaging required for a sterile Class device is shown below. These comply with GHTF/SG1/N43:2005.

The labels are affixed to the container:



Appendix 9 – Technical Files [SOP24] ^x

- Revision History

| Change Note No. | Old Issue | New Issue | Description of Change | Release Date | Approval Signature |
|-----------------|-----------|-----------|--|--------------|---|
| CN 101 | CN01 | 2 | Amended wording to comply with NZ & Australian regulations | 13/7/07 |  |

1. Scope:

This document describes the requirements for preparation, review and approval of a device Technical File.

2. Applicable Documents

4. European Communities Medical Devices Directive (MDD) 93/42/EEC
5. SOP 07 “Document Control”
6. SOP 17 “Quality Records”

3. Definitions

3.1 Competent Authority – the regulatory body within a member state that is charged with ensuring that the provisions of the MDD are correctly implemented. Within New Zealand and Australia the Competent Authority is The Minister of Health.

3.2 Notified Body - the organization, approved by and working on behalf of the Competent Authority that is responsible for ensuring that the device manufacturer complies with all of the relevant requirements of the MDD.

In New Zealand the Notified Body is MEDSAFE, while in Australia the Notified Body it is the Therapeutic Goods Authority (TGA).

4. Responsibilities

4.1 The Managing Director of TawaMed is responsible for the preparation and maintenance of

X Document developed for author's company

Technical Files.

4.2 The Managing Director of TawaMed is responsible for communicating with the Competent Authority and the Notified Body.

5. Procedure

- In order to demonstrate compliance with the relevant requirements of the European Communities Medical Devices Directive (MDD) 93/42/EEC it is necessary to compile a Technical File for each product or family of products.
- A typical structure for a Technical File is detailed in Appendix A to this SOP. The technical information can either all be contained within one physical file or may be located throughout the organization with a contents list identifying the precise location of each piece of information.
- The content of the Technical File needs to address the Essential Requirements detailed in Annex I of the MDD together with the requirements contained within the relevant Annex used for conformity assessment, e.g. Annex VII “EC Declaration of Conformity” clause 3.
- The completed Technical File will be made available for review by the Notified Body as part of their responsibility for assessing compliance with the requirements of the MDD.
- The Technical File will be maintained as a controlled document (i.e. with a document number and issue) in accordance with SOP 07 “Document Control”. A controlled copy of the Technical File will be held in safe keeping by Tawa Medical Holdings Ltd and will be made available to the Competent Authority and the Notified Body when requested.

6. Record Retention

- All records including this SOP shall be retained in accordance with SOP 17 “Quality Records”

Appendix 10 – Document Change Note ^Y

| | |
|--|-------------------|
| Tawa Medical Holdings Ltd 21 st Dec 06 | FRM 06 Issue 1 |
|--|-------------------|

DOCUMENT CHANGE NOTE

| Revision History | | | | | |
|------------------|-----------|-----------|-----------------------|--------------------------|--------------------|
| Change Note No. | Old Issue | New Issue | Description of Change | Release Date | Approval Signature |
| CN 101 | N/A | 1 | New Release | 14 th July 07 | |

Initiator: P J TURNER

Date: 14th July 07

| | | |
|----------------------|---|----------------------------------|
| DCN Number: 00101 | Release Date: 14 th July 07 | Document Control Signature: : |
|----------------------|---|----------------------------------|

| Document Number | Old Iss. | New Iss. | Document Title | | | |
|---|-------------------------------------|------------------------------|-------------------------|-------------------|-----------------|--|
| SOP24 | 1 | 2 | Technical Files – SOP24 | | | |
| Description of Change: | | | | | | |
| Amend doc. to correct ISO references | | | | | | |
| Reason for Change: | | | | | | |
| Invalid references | | | | | | |
| Disposition (check all that apply): | | | | | | |
| On Order | Rec Insp. | Material Stores | WIP | Finished Goods | Field | |
| Use As Is _____ | Use As Is _____ | Use As Is _____ | Use As Is _____ | Use As Is _____ | Use As Is _____ | |
| Rework _____ | Rework _____ | Rework _____ | Rework _____ | Rework _____ | Rework _____ | |
| Scrap _____ | Scrap _____ | Scrap _____ | Scrap _____ | Scrap _____ | Scrap _____ | |
| Areas Affected (check all that apply): | | | | | | |
| Regulatory Files | <input checked="" type="checkbox"/> | Product Specification | _____ | | | |
| Process Validation | _____ | Labelling | _____ | | | |
| Design Validation | _____ | Tooling Equipment Forms | _____ | | | |
| Bill of Material (BOM) | _____ | Work Instructions | _____ | | | |
| Device History Record (DHR) | _____ | Quality Instructions | _____ | | | |
| Device Master Record (DMR) | _____ | Supplier List | _____ | | | |
| Employee Training | _____ | Technical File | _____ | | | |
| Approvals | | | | | | |
| Engineering | | Purchasing/ Manufacturing | Date | Quality Assurance | Date | |
| Regulatory | ✓ Date: 14 th July 07 | Marketing | Date | Other | Date | |

Appendix 11 – SOP 07 - Document Control ^Z

| Revision History | | | | | |
|------------------|-----------|-----------|---|--------------|---|
| Change Note No. | Old Issue | New Issue | Description of Change | Release Date | Approval Signature |
| CN 001 | N/A | 1 | New Release | | |
| CN102 | 1 | 2 | Correction of references & relevance to TawaMed | 14/7/07 |  |

1. Scope:

This document establishes the requirements for the control of the approval, initial issue and distribution of quality system documents and subsequent revisions to those documents.

2. Applicable Documents:

- ISO 13485:2003(E) Quality Systems-Medical Devices-Particular Requirements for the Application of ISO 9001:2000
- ISO 9001:2000 Quality Management Systems – Requirements.
- European Communities Medical Devices Directive (MDD) 93/42/EEC
- SOP 017 “Quality Records”
- SOP 22 “Communication with the Notified Body and the Competent Authority”
- FRM 06 “Document Change Note”
- FRM 07 “Document Change Note Log”

3. Responsibilities

The Managing Director [MD] will be responsible for controlling the issue, distribution and revision of quality system documents.

4. Procedures

4.1 Document Numbering:

4.1.1 QM – Quality Manual

4.1.2 SOP - Standard Operating Procedure

4.1.3 FRM – Form used to record information

Z Document developed for author's company

4.1.4 DCN – Document Change Note

4.1.5 CC – Customer Complaint

4.1.6 TF – Technical File

4.2 Release of New Documents:

- All new documents will be released for use using a completed approved Document Change Note (FRM 06).
- A DCN No. will be allocated from the Document Change Note Log (FRM 07)
- The initiator of the DCN will enter the DCN number, Release Date, sign as Document Control, enter the Document Number, the New Issue Number and the Document Title.
- The Description of Change and Reason for Change will be “Initial Release of Document”. If more than one document is being released by the DCN a list of documents will be compiled and attached to the DCN. Disposition and Areas Affected will not need to be completed.
- Approval for the release of new documents will require the signature of the MD for the DCN. The DCN No. will be entered on the documents being released. These documents will also be signed and dated by the MD. Approval signatures and dates will be entered using blue ink.
- When approved the master original copies of the documents being released and the DCN will be held by the MD in the QMS files.
- When a copy of an approved documents is issued it will be marked as a copy. It is the recipient’s responsibility to ensure that they are using the latest issue of a document.

4.3 Changes to Released Documents:

- All changes to released documents will be authorised by the issue of a completed approved DCN (FRM 06).
- A DCN No. will be allocated from the Document Change Note Log (FRM 07).
- The initiator of the DCN will enter the DCN number, Release Date, sign as Document

Control, enter the Document Number, the New Issue Number, the Document Title, the Description of Change and Reason for Change. If more than one document is being changed a list of documents will be compiled and attached to the DCN.

- The DCN will be reviewed by all of the organisational individuals (see SOP 02 fig1) relevant to any aspect of document alteration featured. All changes are subject to the MD's approval.
- If relevance cannot be identified, then the MD will act as the additional signatory until clarification can be obtained. Manufacturing can be represented by a representative of a sub-contractor, if appropriate. Each reviewer will decide on the Disposition and Areas Affected.
- The MD will also consider whether the proposed change is considered substantial and therefore will need to be considered in accordance with the requirements of SOP 22 "Communication with the Notified Body and the Competent Authority". The DCN will be signed and dated by each reviewer. Approval signatures and dates will be entered using blue ink.
- The DCN No. will be entered on the documents being revised. These documents will also be signed and dated by MD. Approval signatures and dates will be entered using blue ink.
- When approved the revised master original copies of the documents and the DCN will be held by the MD in the QMS files.
- The recipient of revised documents will be responsible for ensuring that any superseded copies of documents in their possession are destroyed.
- One copy of obsolete changed documents will be stamped "Obsolete" and retained in the QMS files as a historical record. Obsolete documents will be segregated from current issue documents, placed in the VOID file and will not be available for use.

4.4 External Documents

- A listing of external standards and regulatory documents will be held and maintained by the MD.
- The listing will be reviewed at six monthly intervals to ensure that the latest version is held.
- Out of date copies of external documents will be withdrawn and destroyed.

5. Record Retention

5.1 All records including this SOP will be retained in accordance with SOP 17 "Quality Records".

Appendix 12 – Pre Market Approvals

Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III pre-amendment devices may require a Class III 510(k). See "[Historical Background](#)" below for additional information. ¹¹⁸

The following exemptions or waivers apply.

| Fee Exemptions and Waivers (No Fee for These) | |
|--|---|
| Category | Exemption or Waiver |
| <i>First</i> premarket application (PMA, PDP, BLA, or premarket report) from a small business with gross receipts or sales <\$30 million . | One-time waiver of the fee that would otherwise apply. |
| Any application for a device intended solely for pediatric use. | Exempt from any fee. If an applicant obtains an exemption under this provision, and later submits a supplement for adult use, that supplement is subject to the fee then in effect for an original premarket application. |
| Any application from a State or Federal Government entity. | Exempt from any fee unless the device is to be distributed commercially. |

If the Pre Market process is required for a non-exempt Class III MD or it is not a first application the fees are considerable. See below.

Fees

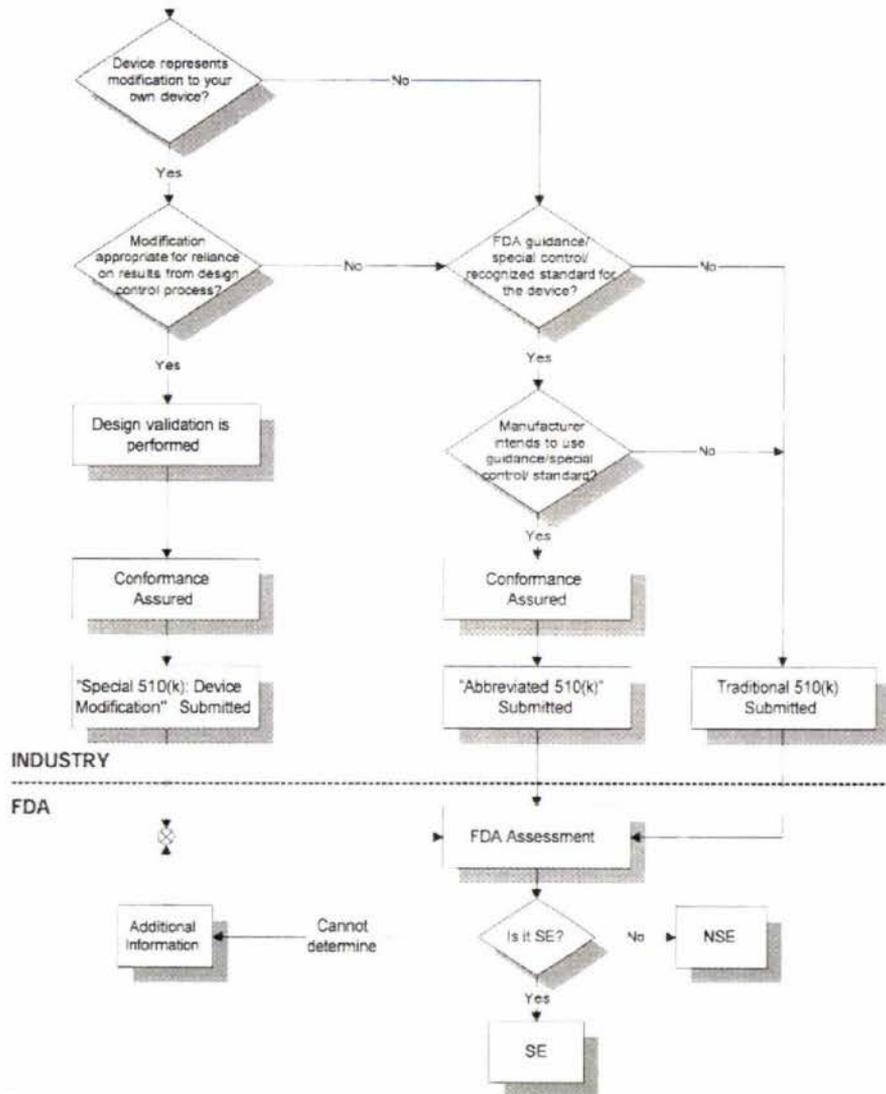
For fiscal year 2007 (October 1, 2006 through September 30, 2007), the fees for PMA applications are:

| FY 2007 Device Review User Fees (U.S. Dollars) | | |
|---|---------------------|--|
| <i>Type of Application</i> | <i>Standard Fee</i> | <i><u>Small Business Fee</u></i> <i>(<\$100 million sales)</i> |
| Premarket Application (PMA, PDP, BLA, PMR)* NOTE: The fee is waived for the <i>first</i> premarket application from firms with gross receipts or sales < \$30 million. | \$281,600 | \$107,008 |
| Premarket Report (PMR) - premarket approval application for a reprocessed device | \$281,600 | \$107,008 |
| Panel-track Supplement | \$281,600 | \$107,008 |
| Efficacy Supplement (for BLA) | \$281,600 | \$107,008 |
| 180-day Supplement | \$60,544 | \$23,007 |
| Real-time Supplement | \$20,275 | \$7,705 |

* PMA=Premarket Approval; PDP=Product Development Protocol; BLA=Biologics License Application; PMR=Premarket Report (for a reprocessed device)

The New 510(k) Paradigm

Intent to Market a Device
 for Which a 510(k) is Required



This flowchart should only be considered in conjunction with the accompanying proposed text.

Appendix 13 – MATCH Deliverable 6A

Summary of Key Issues, Findings and Conclusions ¹²¹

Users and end-users:

- *End-users were predominantly perceived to be clinicians rather than patients and were mainly involved in the post-market surveillance stage of device development. The key issue extrapolated in relation to patterns of end-user involvement is the requirement for value to be placed on the individual enduser, their social group, together with healthcare professionals throughout the stages of device development. A cluster of exemplary cases illustrated components of user and end-user engagement including 'locking-in' manufacturers in partnerships with academics, clinicians, engineers and ergonomics.*
- *Inclusion of both user and end-user information is crucial to the successful outcomes of medical devices in an episode of treatment and care. This suggests that a cluster of methods will be needed for the life cycle of any given device requiring established strategies for sourcing information.*
- *Sampling strategies also need to be carefully structured to include individuals with complex medical diseases and conditions in order to conduct evaluations that provide meaningful outcome measures. A focus on sampling methodologies and small group sampling techniques may address this gap.*

The context of medical device usage:

- *Unless devices are examined in the context in which they are used, including the cultural and environmental context, the effectiveness and usage of the devices will be limited. The export of medical devices without regard for local customs, norms and resources including materials and skills, has significant implications for global trade and export of medical devices.*

The context of tools used in medical device evaluation:

- *There is a need for conceptual clarity in tool development that takes into account key domains of medical device users and the context of device use. This clarity is particularly important for generating meaningful outcome measures of device performance including the definition of end points in health technology assessment.*

Methods to Capture User Perspectives - Part A

Issues were raised regarding the validity, reliability and sensitivity of generic tools, highlighting the need to develop context specific device related tools that generate reliable and robust data.

Major Recommendations

The findings indicate a review of methodologies for medical device evaluation. Specifically there is a need for the following:

- *Harmonised methodologies and methods underpinned by valid clinical theories in which the end-user is more prominent in the stages of medical device development and evaluation, including post-market surveillance.*
- *Methods need to be capable of capturing relevant contextual variables and device performance end-points, taking account of the maturity of device technologies and multiple stakeholder perspectives.*
- *The methodologies must be usable in the fast paced arena of medical device technologies and commercial interests.*
- *The onus is on academic researchers, in consultation with key stakeholders including industry, to develop and validate methodologies and tools that represent user and end-user needs to industry, to influence the development of user focused products.*
- *The recommendation from this report is for collaboration with experts from the social sciences, healthcare, health economics and industry to guide the development of methodologies for medical device evaluation.*