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

by

Peter J Turner

A thesis submitted in fulfillment of the requirements for the degree
of

Master of Technology (MTech)

Massey University

2003 - 2007

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

Acknowledgements.

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.

I wish to express my gratitude to my supervisors Dr Kevin Low and Prof. Allan Anderson who have directed me down the path.

To my partner, Dr Kathy Stone who has never wavered from her commitment to support me in this endeavour.

To my colleagues: Martyn Cook, Paul Sinding & Wolf Marbach against whom I have batted ideas and who have provided me with perspective, thank you.

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 ultise 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.

by Peter J. Turner

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 it's 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 it's operation and optimise it's 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 facilitiate the process and an infrastructure to support it.

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