Overview of Medical Device Development

Business over Breakfast
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Research ≠ Development

Research Prototype vs. Commercial Product

- Safe enough
- Built by dedicated Engineers
- Usable by Key Opinion Leaders with guidance from Inventor
- Has to work during a demo
- Cost not a primary consideration

- Safe enough to use on your mother
- Built on the production line by workers at minimum wage
- Usable by clinical doctors, nurses, and technicians under high stress
- Has to work every time
- Must be cost-effective

Take Home Message

In the United States in 2014 there were 2,823 medical device recalls resulting from 116,000 injuries and 4,500 deaths

It is our responsibility to make devices safe

Objectives of Product Development

Develop a product that:

- The market wants and will pay for
- Will make a material difference in patient outcomes
- Safe
- Reliable
- Easy to use
- Can get regulatory approval
- Manufacturable at a reasonable cost
- Can get IP protection

Development Standards and Tools

- Quality System – ISO 13485 and FDA 21CFR part 820
  - Design Control
  - Document Control
  - Change Control
- Risk Management – ISO 14971
- Human Factors – IEC 62366
- Medical Device Standards – IEC 60601
- Software Lifecycle – IEC 62304
- Biocompatibility – ISO 10993
- Regulatory Requirements – FDA, Health Canada, MDD, CFDA, PMDA
- Clinical Trial management – ISO 14155 (Good Clinical Practice)
- Almost every type of product and every process has an associated standard – e.g. sterilization, packaging, shipping, labeling, etc.

Quality System – ISO 13485

- Quality is not simply working hard and trying your best. It is the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements
- A formal, all encompassing structure that guides every single process and activity at a company through the use of Standard Operating Procedures
- It affects all departments of the company and forms the basis of all activities, including product development
- The culture of a successful medical device company is focused on its quality system

ISO 13485: Design Control

- A method where product development is divided into stages, and stages are gated – the company must hold a formal Design Review in order to pass through a gate to the next stage
- Principles:
  - All development is based on forming and meeting requirements
  - Test procedures are written before the product is designed
- Typical Stages:
  - Concept
  - Planning
  - Design
  - Verification and Validation
  - Design Transfer

Concept Phase

- Marketing Requirements
- Proof of technical feasibility
- Validation Plan
- Risk analysis and mitigation
- Regulatory Plan
- IP Plan
- Business Case

A new project is a serious undertaking – the Concept Phase is a lot of work

Planning Phase

- Design Inputs – functional specifications
- System architecture
- Software architecture
- Verification Plan
- Detailed hazard analysis and mitigation plan

By the end of the Planning Phase, you know have done the conceptual design!

Design Phase

- Design outputs – schematics, source code, drawings
- Failure Mode and Effects Analysis
- Device Master Record
- Design History File

V & V Phase

- Verification: do Design Outputs satisfy Design Inputs?
  - Bench testing
  - Pre-clinical testing
  - Standards testing
- Validation: Does the product satisfy Marketing Requirements?
  - Usability testing
  - Clinical testing

Design Transfer Phase

- Manufacturing procedures
- Risk management
- Process validation

The amount of effort and time involved in Design Transfer is consistently underestimated

Take Home Messages

Embrace the Regulations, do not fight them – the huge amount of effort really works - they are the key to excellence in Medical Devices

Regulations are guidelines open to interpretation – every company implements things differently

Regulations change – most have new versions every 5 years. Keep up to date!

Risk Management – ISO 14971

- A formal method of analyzing, evaluating, and controlling risks presented by the product to patients and operators
- Recognizes that not all risks can be eliminated and provides a mechanism for residual risk evaluation
- Requirements for reporting during design, manufacturing, and post marketing
- Over the last few years, Risk Management has been incorporated into all other development tools – including ISO 13485 and IEC 60601 – and has become the central focus of product development

Human Factors - IEC 62366

- Usability distinguishes a great medical device from a good medical device
- It aims to improve usability by reducing design-induced error
- Human Factors methodology:
  - Design
    - Who will be using the device - what training do they have, what disabilities and physical limitations might they have?
    - Where will the device will be used – lighting, noise levels, temperature?
    - How quickly does the device have to respond?
    - How transportable does the device have to be?
  - Testing
    - Formal testing to reveal usability, effectiveness of training, common errors

Medical Device Standards – IEC 60601

- One standard for device safety accepted world-wide
- 60601-1 Basic Safety and Essential Performance for Medical Electrical Systems
  - 420 pages
  - Covers leakage current, defibrillator safety, wiring and spacing, mechanical strength, thermal management, alarm systems, markings, etc…
- 60601-1-2 Electromagnetic Compatibility
  - Covers radiation, susceptibility, resistance to power line transients, brownouts, and electrostatic discharge
- 60601-2 Particular requirements for special types of devices
  - e.g. x-ray, ultrasound, ECG, etc…
  - 54 different standards

Software Lifecycle - IEC 62304

Core processes:

- Software development process
- Software maintenance process
- Software risk management process
- Software configuration management process
- Software problem resolution process
- Classes:
  - Class A: No injury or damage to health is possible
  - Class B: Non-SERIOUS INJURY is possible
  - Class C: Death or SERIOUS INJURY is possible

Biocompatibility – ISO 10993

Biocompatibility testing answers the following questions:

- Is the material safe?
- Does it have the necessary physical and mechanical properties for its proposed function?

The amount of testing depends on:

- Type of material
- End use – casual contact through to permanent implant, skin contact through to blood contact
- Function of the material within the device
- Availability of existing data on the material

Regulatory Requirements

Safety:

- Prove that your company has a certified quality system
- Prove that your device was developed according to all of the appropriate standards
- Prove that your device is safe in clinical use

Efficacy:

- Prove that your device provides the medical benefits that you claim

Clinical Trial Management - ISO 14155

- Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice is a standard for designing, conducting, performing, monitoring, auditing, recording, analyzing and reporting clinical trials
- Provides assurance that data and reported results are credible and accurate and that the rights and confidentiality of subjects are protected

Conclusions

- Developing a medical device through to commercialization is a long, difficult, and expensive process
- Embracing the standards and regulations that govern this process will lead to safe, reliable devices that will benefit thousands of patients, make you proud, and make you rich

Thank you

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