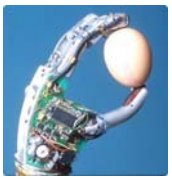
ResMed
Changing lives with every breath

Medical Devices: From Concept to Reality

Klaus Schindhelm

ENGG 1000 Project



- Was the definition adequate?
- Were there any limitations?
- Was any negotiation involved in the specifications?
- How were issues resolved?
- Is it technically appropriate?
- Are you meeting the customer need?
- Was there a tradeoff between specifications and reality?

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ENGG 1000 Project

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- How were issues resolved?
- Is it technically appropriate?
- Are you meeting the customer need?
- Was there a tradeoff between specifications and reality?
- Market requirements?
- $ / time /performance?
- System design?
- Internal negotiation?
- Verification?
- Validation?
- Market success?

Design Control

Design Control = Regulatory Recipe for Product Development

WHY IS BIOMEDICAL TECHNOLOGY REGULATED?

The primary objective of medical device regulation is the protection of public health and safety by ensuring the **quality**, **safety** and **efficacy** of the medical devices generally available for the treatment of the general public.

Design Control Regulation

REGULATORY FRAMEWORKS

- **FDA QS/GMPs Regulation Final Rule**
- **510(k), PMA, IDE, Computer/Software**
- **ISO 9001, EN 46001**
- **CE Mark**

PENALTIES

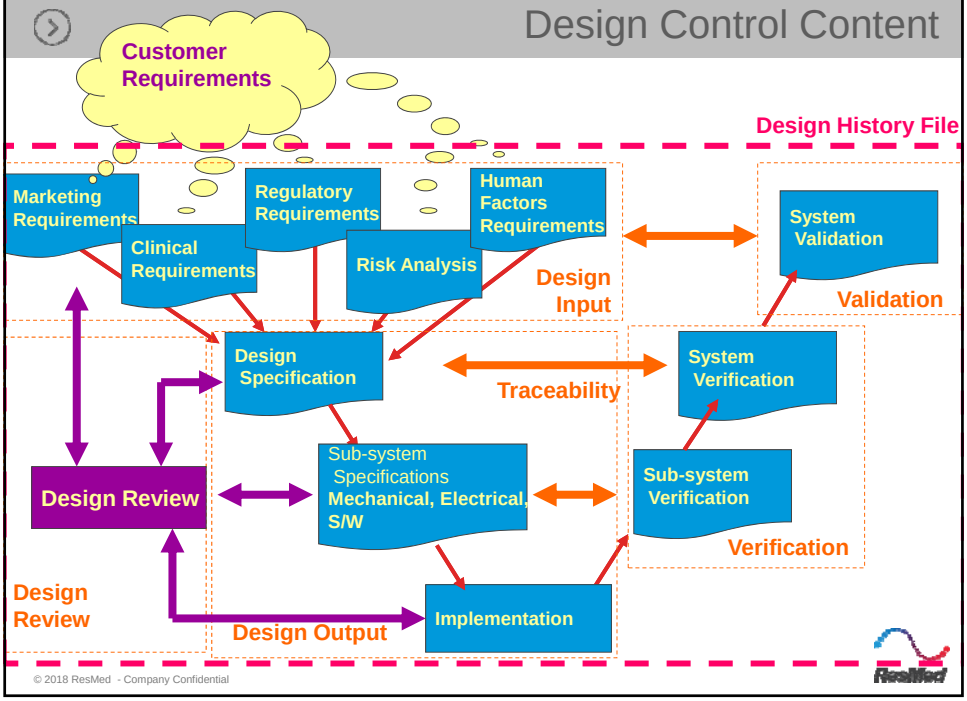
- **Fines**
- **Imprisonment**

Design Control Requirements (FDA)

Sec. 820.30 Design controls.

(a) General (Class II & III devices require design controls).
(b) Design and development planning.
(c) Design input.
(d) Design output.
(e) Design review.
(f) Design verification.
(g) Design validation.
(h) Design transfer.
(i) Design changes.
(j) Design history file.

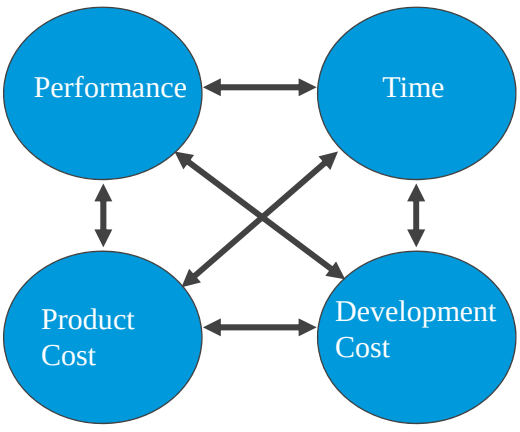
Design Control Content



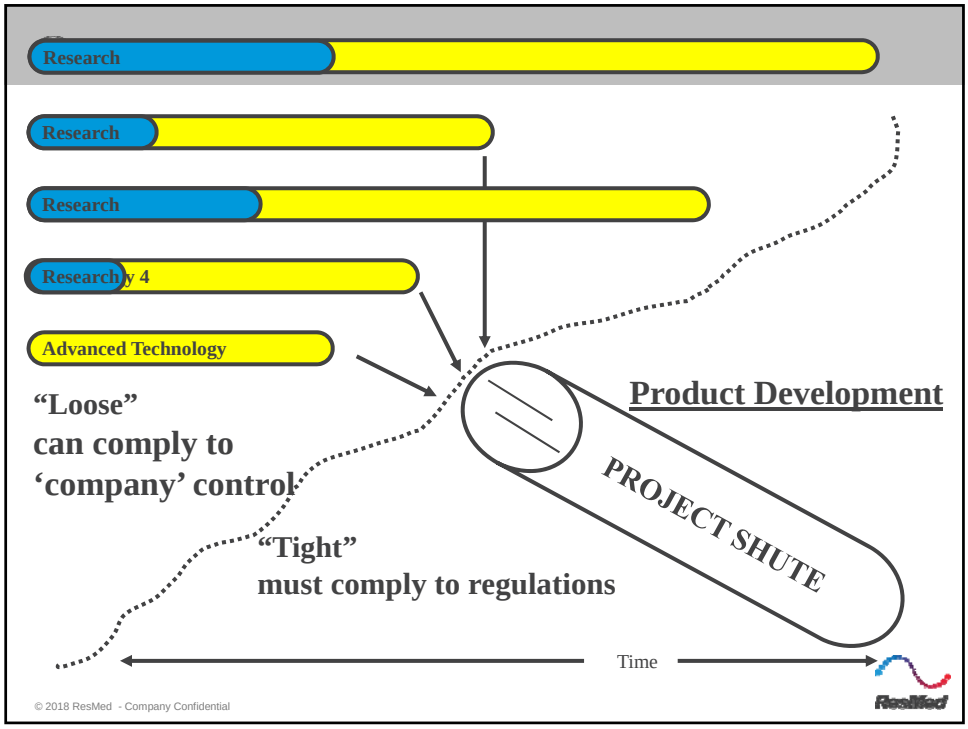
GOALS OF EFFECTIVE DESIGN CONTROL

Time to market
Superior product
Lower cost of product
Regulatory compliance

CONSIDERATIONS IN PRODUCT DEVELOPMENT



Adapted from New Product Dynamics, 1999

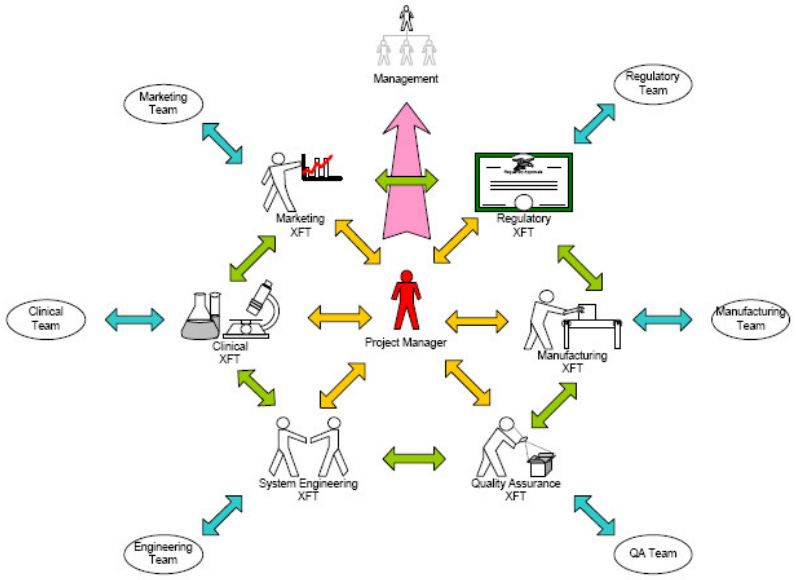


Product Development in ResMed

1. Establish Cross Functional Team (XFT)
2. Gather "appropriate" input.
3. Obtain Senior Management approval.
4. Have "Kick-off" meeting to establish specs.
5. Start project under ResMed procedures (AQP101).

ResMed

Cross Functional Teams



AQP101

Product Development Procedure

AQP101

Rev 10.0

1. **Overview**

1.1 **Purpose**	This procedure defines; • The normal progression of activities required to successfully develop a product which meets worldwide statutory requirements and ResMed's quality requirements. • The interrelationship between departments through the establishment of an XFT
1.2 **Scope**	This procedure applies to • All new products developed and released by ResMed, its subsidiaries or partners. • The sequence of events to design a product that meets – Customer needs, – Design intent, – Expected quality levels, – Business expectations for the product.

AQP101

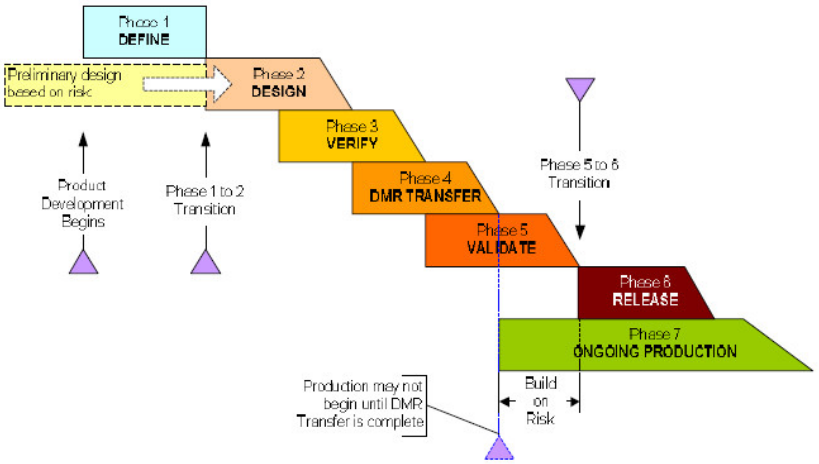


Figure 2 - Phase Approach to Concurrent Engineering