Imaging product development; from concept to a clinical device

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Disclosures

- Employee, Canon Medical Systems

Where does medical technology come from?

Whose idea was this anyway?

Product conception

- Technology development ideas come from everywhere
  - Users (customers)
  - Market trends analysis
  - Academia (research collaborations or independent)
  - Focus groups
    - Internal ex: Clinical Trends
    - External ex: MAB
  - Industry scientists (hey, what if we try this…?)
  - Regulatory (FDA, etc.)
  - Professional Organizations (AAPM, IEC, MITA, etc.)
  - etc.

Example

Who decides if an idea is worth consideration for development?

Vetting the idea

- This is decided on by the R&D and business teams based on info from:
  - Market Needs (including all regions globally)
  - Clinical trends groups (internal)
  - Medical Advisory Boards (external)
  - Regulatory drivers

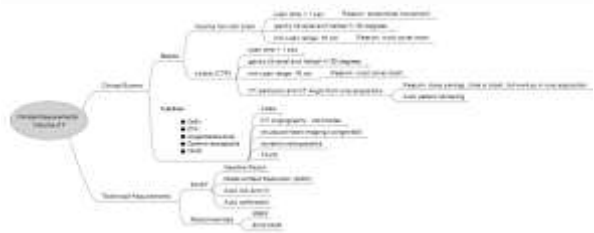
MAB = Medical Advisory Board

Turning an idea into reality

Develop detailed product consideration documents

- Product Specifications
- Intended Use
- Costs considerations
- Priorities

Mind Map to determine specifications



Simulated Example

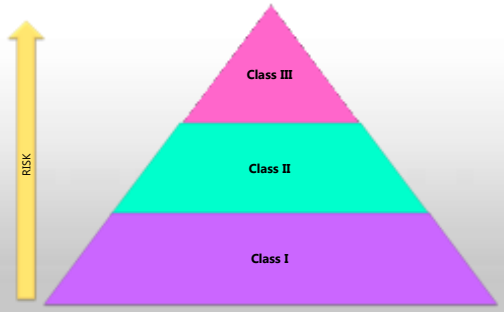
Do we really want to commit to this?

Vetting the idea (again)

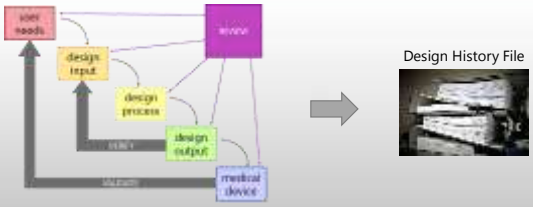
- Reassess the proposal with business plan.
  - Development cost (time and $)
  - Opportunity cost: What other projects do we have to delay to develop this technology?
  - Supplier considerations
  - Business Impact (revenue, training costs, etc.)
  - Clinical/Regulatory risks
    - ➔ FDA related risks (e.g., MyoCTP)?
    - ➔ Reimbursement considerations (can customers charge for it?)

Time to get started!

- Engineering Development
  - hardware vs. software
  - FDA Class I, II, or III device
  - etc.



Design Control



Design History File

Adapted from: U.S. Food and Drug Administration, "Design Control Guidance for Medical Device Manufacturers", Guidance for Industry and Food and Drug Administration Staff, issued March 11, 1997.

Clinical Validation

- ✓ Design Control is complete
- ✓ Regulatory product clearance
- ✓ Product is complete!

- ➢ Not done yet!
  - Clinical Validation studies
  - Economic impact studies
  - Use examples
  - Marketing materials/ brochures
  - White papers
  - etc.