Medical Device Innovation

From Discovery & Ideation to Market

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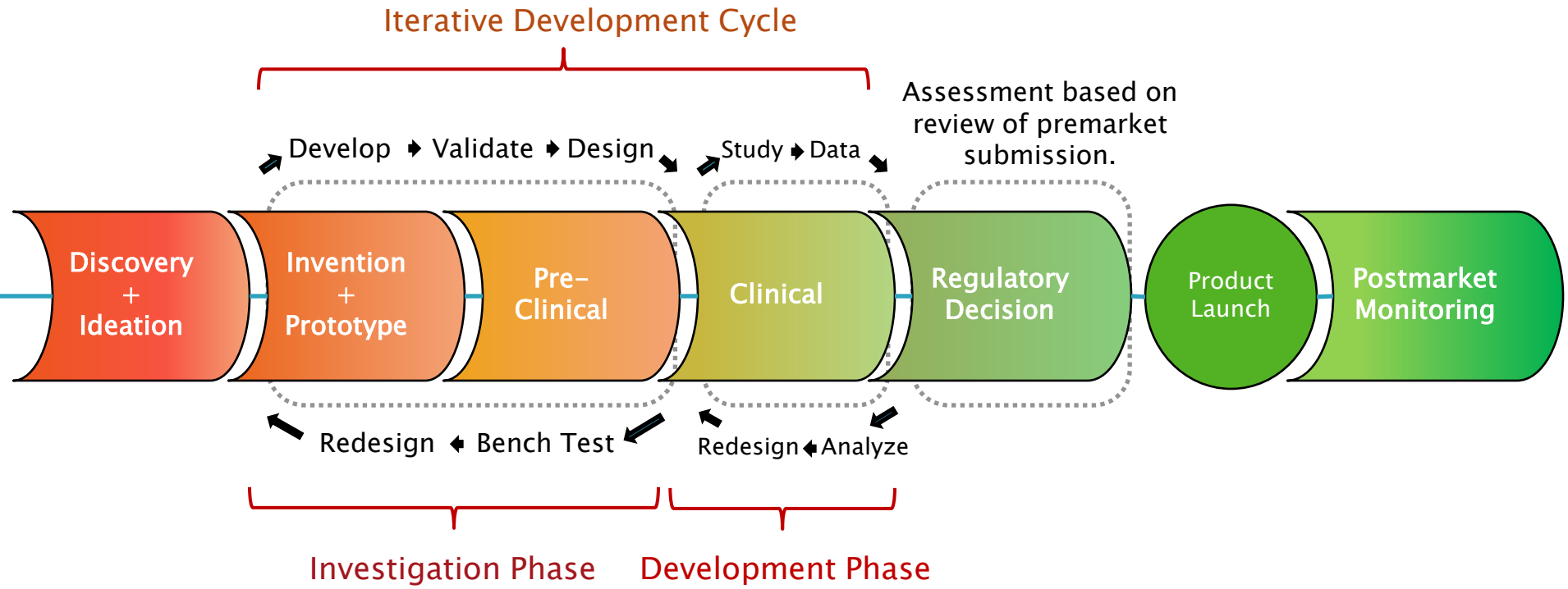
Topics

1) Device Discovery and Ideation
2) Medical Device Regulations
3) Product Life Cycle
4) Design Controls
5) Medical Device Testing
6) Risk Management
7) Quality Assurance

Medical Device Development Pathway



Adopted from CDRH *Innovation Initiative*, February 2011.

Development Process

Determining Market Opportunity
- Do competitive & market analysis
- Decide key markets
- Expense & funding Options

Develop Early Sample Prototype
- Disruptive technology
- Market potential
- Key validators
- Is this a venture Quality Deal?
- Business startup

Converting Patent or Filing Global PCT
- Determine Product Development Plan
- Proof of Concept
- Evaluate FDA and CE Mark Details
- Evaluate your exit strategy

Choosing and Coordinating Proper Engineers
- Complete working prototype
- Do initial business plan
- Funding needs

Properly Choosing Best Industry Experts as partners for Technology & evaluation

Adopted from *The Medical Device Product Development Process*, Compliance4All. https://www.compliance4all.com/control/medical-device-product-development-process

1) Discovery & Ideation

- Where do discoveries and ideas come from?
  - Entrepreneurs
  - Government
  - Medical device companies
  - Patients
  - Physicians
  - University researchers
  - and You!

Is There A Need?

- Need driven rather than technology driven.
  - Select a clinical area.
  - Observe procedures.
  - What is the underlying problem?
  - Create a need statement.
    - "A way to reduce back pain with bending"
      - NOT "A device to immobilize the back."
  - Brainstorm solutions.
  - Perform a business analysis.

Adopted from Tolkoff, J, *Ideation in Medical Device Development: Finding Clinic Needs*, CIMIT CRAASH Course. cimet.org.

Ideation Session…

- Understand the problem.
- Define an acceptable degree of *transcendence* – deviation from existing ideas and solutions.
- Resources available – your *Team.*
- Structuring the meeting.
- Sources of inspiration.
- Good practices (Osborn, A.T. *Applied Imagination*)
  - Go for quantity.
  - Encourage unexpected ideas.
  - Defer judgment.
  - Combine and improve ideas.

Rudolph, J. *Effectively selecting ideation methods for medical product development*. MedTech Intelligence. January 4, 2012.

Ideation Session…

- Provide breaks.
- Create and enforce rules.
  - e.g. stay focused, do not tell stories and do not criticize.
- Getting stuck.
- Positive motivation and incentive.
- Concluding thoughts.
  - Document the session – process, people involved, sources of inspiration.

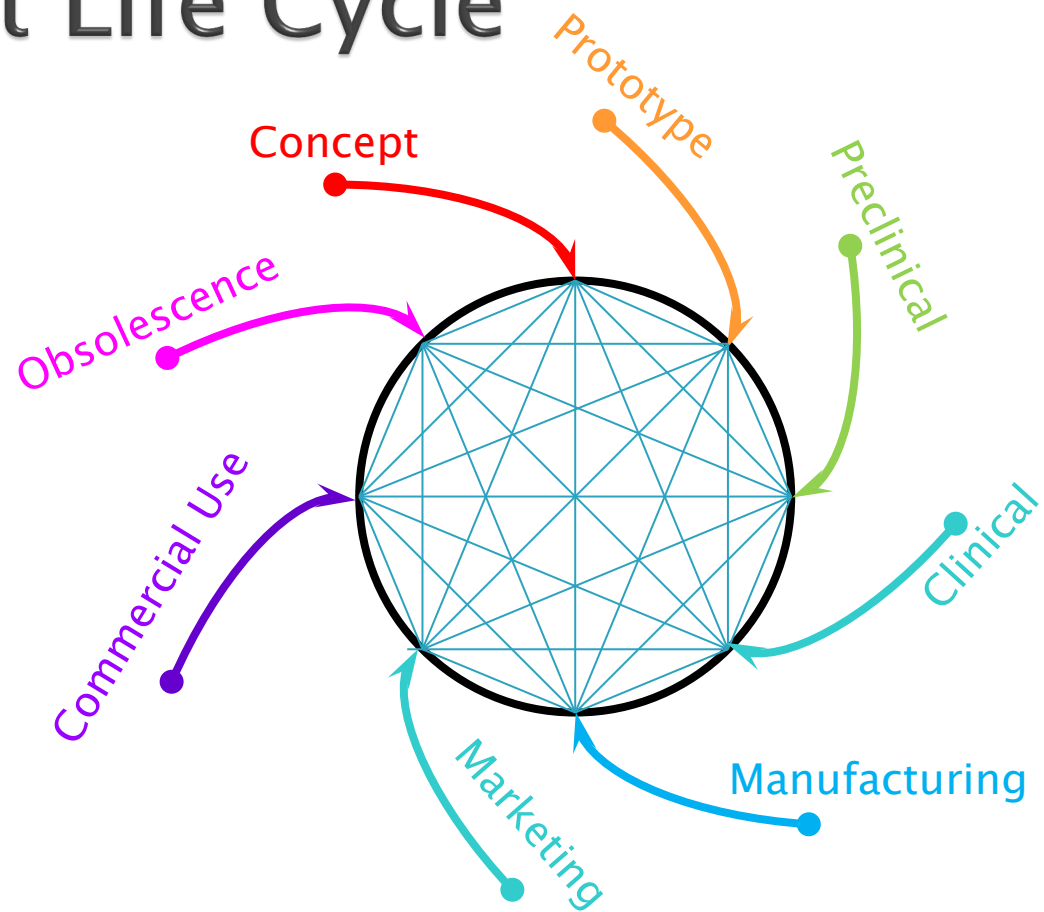
Rudolph, J. *Effectively selecting ideation methods for medical product development*. MedTech Intelligence. January 4, 2012.

2) FDA Regulation

- Premarket Requirements
  - Product Classification – Type I, II or III
  - Premarket Approval (PMA)
    - PMA Supplements.
    - Evaluations of the PMA and PMA Supplement Process.
    - Humanitarian Device Exemption (HDE).
  - 510(k) Notification – Substantially Equivalent Device
    - Assessments of the 510(k) Process
- Post-Market Requirements
  - Postmarket Surveillance Studies.
    - Adverse Event Reporting, Medical Device Tracking, UDI (Unique Device ID)
  - National Medical Device Evaluation System.
  - Labeling and Manufacturing
  - Compliance and Enforcement

3) Total Product Life Cycle

"Medical device development is an iterative process that rapidly incorporates preclinical, clinical, and manufacturing experience into next-generation concept and design."



Adopted from CDRH *Innovation Initiative*, February 2011. (Center for Devices and Radiological Health)

4) Design Controls

- A set/framework of quality practices and procedures incorporated into the design and development process.
- Control the design process – Premarket and Postmarket – to assure that device specifications meet *user needs* and *intended use(s)*.
- They set medical device Quality Systems apart from Good Manufacturing Practices.
  - **cGMPs → QSRs**

Li, S. Design Controls. FDA Small Business Regulatory Education for Industry. FDA. September 2015.

Design Control Scope…

- Design controls apply to *all* **Class II** and **III**, and the following **Class I** devices:
  - Devices automated with computer software
  - Tracheobronchial suction catheters
  - Surgeon's gloves
  - Protective restraints
  - Manual radionuclide applicator system
  - Radionuclide teletherapy source
- Applying Premarket
  - *After* Feasibility/"Proof of Concept"/Prototyping
  - Point where you are designing the *final* product
  - *Prior* to commencement of any Clinical Investigation (21 CFR 812)
  - Mechanism of *change*/revision during any Clinical Investigation (21 CFR812)

Li, S. Design Controls. FDA Small Business Regulatory Education for Industry. FDA. September 2015.

Design & Development Planning…

- Procedures are established, maintained, and documented to:
  - Describe or reference design and development ***activities***.
  - Identify, describe, and define ***interfaces***, r***esponsibilities***, and ***activities*** impacting device design.
  - Review, document, approve, and update as developments and changes ***evolve***.

Li, S. Design Controls. FDA Small Business Regulatory Education for Industry. FDA. September 2015.

Design Controls…

- Design and development planning
  - This is a plan in which the design and development activities are planned by the manufacturer.
- Design input
  - This stage of the medical device product development process takes into consideration all the parameters for making the medical device successful, such as safety, performance, risk, profit and so on.
- Design output
  - This is a set of test, specifications or processes needed to check that the device functions properly.
- Design review
  - The stage of the medical device product development process in which the device is thoroughly checked for defects and corrected.

The Medical Device Product Development Process, Compliance4All. https://www.compliance4all.com/control/medical-device-product-development-process

Design Controls…

- Design verification
  - This stage confirms that the device design is able to withstand a series of tests and challenges and documents the results.
- Design validation
  - This stage uses objective means to examine the device design and confirm if the design output meets the intended use, predictably and demonstrably over a period of time.
- Design changes
  - These are to make sure that the changes, if and when they are incorporated at any stage of the medical device product development process, are approved and implemented.

The Medical Device Product Development Process, Compliance4All. https://www.compliance4all.com/control/medical-device-product-development-process

Design Controls…

- Design transfer
  - The transition stage from device design to production while meeting specifications.
- Design history file
  - A complete record of the stages of the history of the design process which demonstrates that the design was carried out in compliance with design controls prescribed by regulatory authorities.

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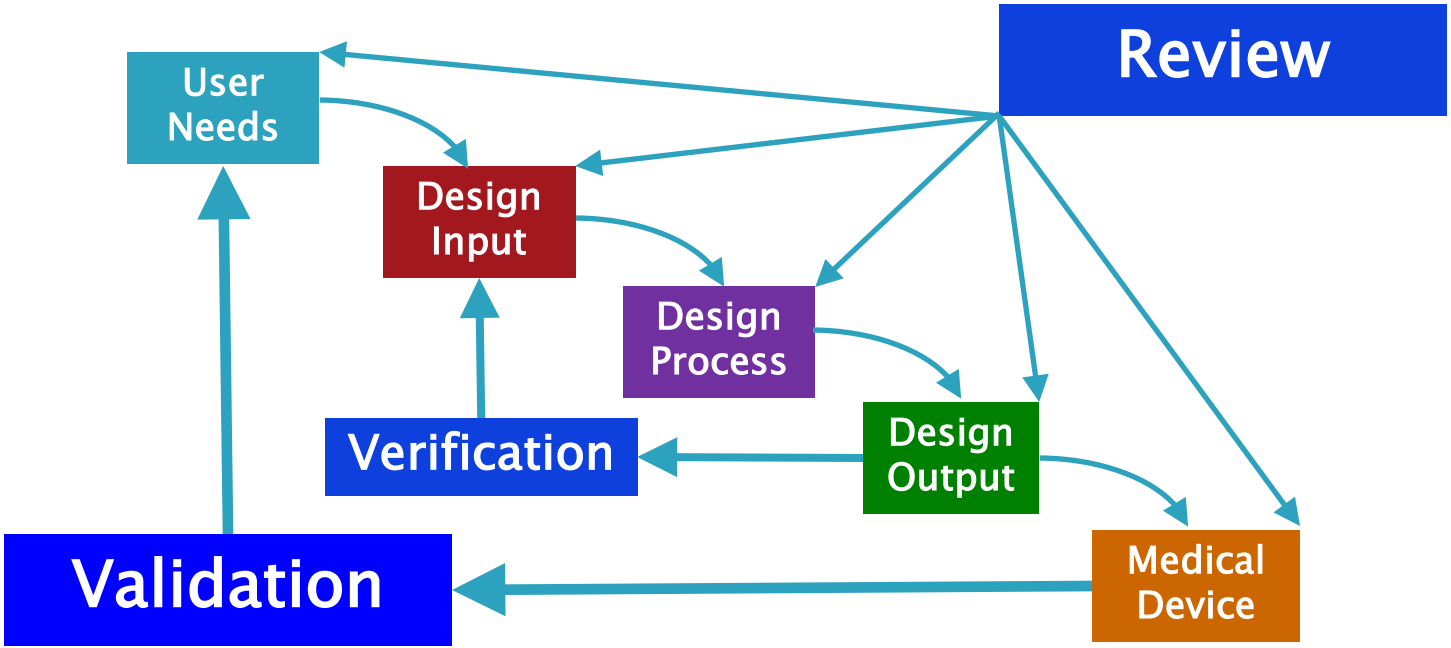
Waterfall Design Process…



Adopted from Medical Devices Bureau, Health Canada

Example – Infusion Pump…

User Need - Pump must function in an operating room environment.

Design Input – Pump must function uninterrupted when used with other products that generate an electromagnetic field.

Design Output – (1) PCB with filtering, (2) Pump EMI shield, (3) software signal filtering code and error handling code.

Design Review

Design Verification – (1) Simulated EMI testing on hardware and software, (2) Dimensional verification shield, (3) Verification of system error handling due to EMI.

Design Validation – (1) EMC testing to industry standards, (2) simulated EMI testing in high EMI environment, (3) *Risk analysis* converting EMI, (4) *Software validation* for filtering code.

Li, S. Design Controls. FDA Small Business Regulatory Education for Industry. FDA. September 2015.

5) Medical Device Testing

- Determined from Various Standards
  - Biocompatibility
  - Investigations of Ophthalmic Devices.
  - Materials Characterization and Analytical Chemistry.
  - Microbiology/Virological Testing.
  - Shelf Life Testing of Devices and Packaging.
  - Validation of Cleaning, Reprocessing and Sterilization.
  - et al.

Why Create a Test Strategy?

- To control and reduce the costs of tests.
- To control the test period and offer protection against a delay in placing the device on the market.
- To take full account of standards applicable to your product in the targeted countries.
- To anticipate the evaluation of material changes/future variants of the device.
- To identify success factors for exporting your medical device in advance.

Medical Devices: Guide to defining a test strategy. LNE, November 2014.

Defining the Test Strategy…

- Identify the *target country(-ies)* to sell your Medical Device and the applicable standards.
- Define the *date* for placing it on the market and identify the versions of standards to be used.
- Consider the developments of an MD.
- *Identify the laboratory(-ies)* to which the tests are to be contracted.
- Anticipate the *sequence* of tests.
- *Present* the test results and conclusions.

Medical Devices: Guide to defining a test strategy. LNE, November 2014.

6) Risk Management

TABLE I: Design control and risk management activities.

Design Step/Phase	Risk Management Activities	Risk Management Output
Design and development planning	Identify intended use and hazards Risk management Plan commensurate with risk	Hazards list Risk management plan
Design input	Hazard identification Risk estimation	Preliminary or initial hazards analysis
Design	Risk estimation and risk evaluation Design mitigations Determine essential outputs	Fault tree analysis Failure modes effects analysis (FMEA)
Verification and validation	Traceability analysis test in normal and fault modes V&V activities commensurate with risk	Traceability matrix V&V test results
Design reviews	Risk evaluations—review risk acceptability Risk and safety part of decision processes	Risk decisions Justify residual risk
Design transfer	Process risk assessment Final safety decision	FMEA Risk summary report
Design change control	Re-assess existing and potential new hazards/risks	Updated risk documents

Rodriquez, J. How to develop an effective design control program: A life-cycle multiphase approach. J GXP Compliance. 12(4) pp.74-83, 2008.

7) Quality Assurance

- A *quality management system* must demonstrate an ability to provide devices and services that *"consistently meet customer and applicable regulatory requirements."*
  - Design and development
  - Production
  - Storage and distribution
  - Installation
  - Servicing
  - Provision of related services and activities (such as technical support)

Pontius, N. The Ultimate Guide to Medical Device Design and Development. Pannam Imaging. April, 2017. https://www.pannam.com

Quality Management System (QMS)…

- Purpose
  - Waste reduction
  - Process improvement
  - Cost reduction
  - Identifying needs and opportunities for training
  - Engaging staff
  - Providing organization-wide direction

Pontius, N. The Ultimate Guide to Medical Device Design and Development. Pannam Imaging. April, 2017. https://www.pannam.com

Quality Management System (QMS)…

- Critical Elements
  - The company's quality policy
  - Quality objectives
  - Procedures, manuals, and instructions
  - Internal processes
  - Data management
  - Customer satisfaction data
  - Quality analysis and areas for improvement.

Summary

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