Regulatory, quality and clinical affairs

NX-451 – What to know when working with medical devices

Session 4

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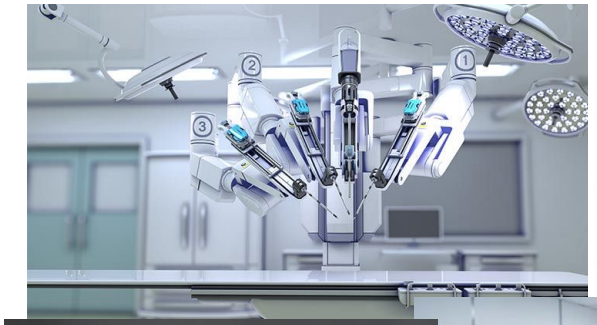
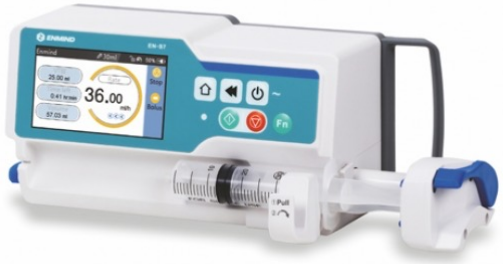
Medical device design and development





Medical devices are used to treat patients, but they also represent a great deal of risks for them

Medical device design and development

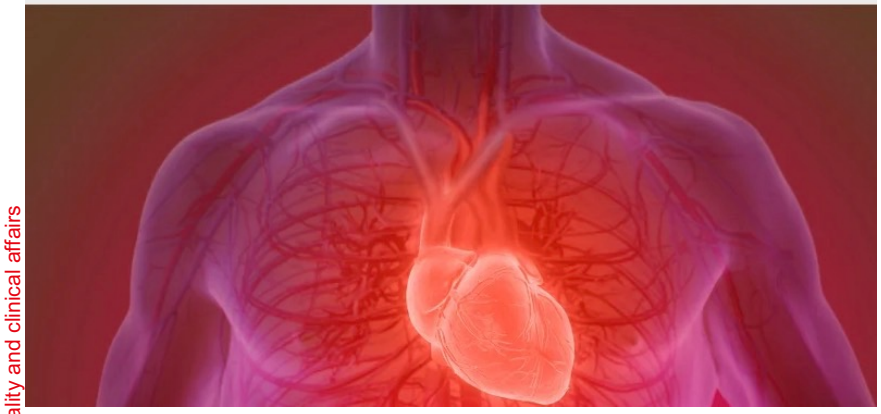
Johns Hopkins study suggests medical errors are third-leading cause of death in the US with 250’000 patients (ca. 9.5% of all deaths each year in US)*

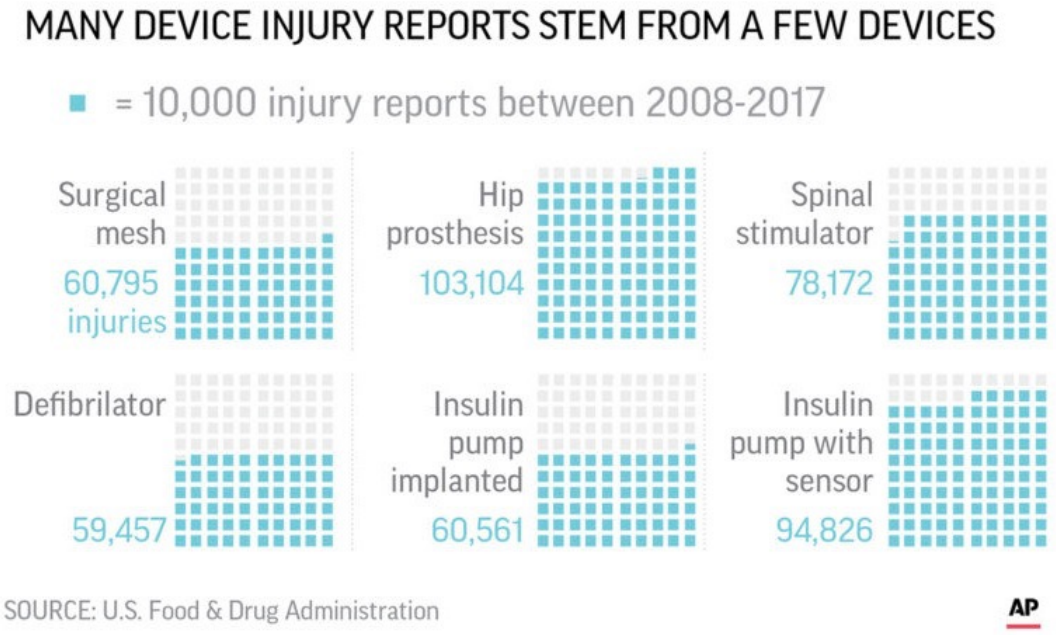
APRIL 17, 2024 | 5 MIN READ

FDA Recalls Heart Pumps Linked to Deaths and Injuries

Two medical devices that mechanically pump blood to the heart have caused hundreds of injuries and more than a dozen deaths

BY DANIEL CHANG, HOLLY K. HACKER & KFF HEALTH NEWS





There were 1,048 medical device recalls in 2024, an increase of almost 25% from the 840 recalls that occurred in 2023, according to the Food and Drug Administration

*Source: https://hub.jhu.edu/2016/05/03/medical-errors-third-leading-cause-of-death/
https://www.modernhealthcare.com/digital-health/medical-device-recalls-fda-2024

MD design and development – in general

Design or manufacturing failures occur…

Medtronic MiniMed insulin pumps
Vulnerability was identified that could lead to malicious instruction to the pump to modify the dosage.

Edwards Lifesciences monitoring platforms
Users were informed that fluids could leak into the device AC power outlet which could result in an electrical short circuit.

FLOW-i anesthesia systems
The FLOW-i anaesthesia delivery system administers anaesthetic while also providing ventilation to patients with little or no ability to breathe. Patient cassettes, which are the centre of the gas flow in the system, came loose, causing anesthesia gas to leak from the device

MD design and development – in general

GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

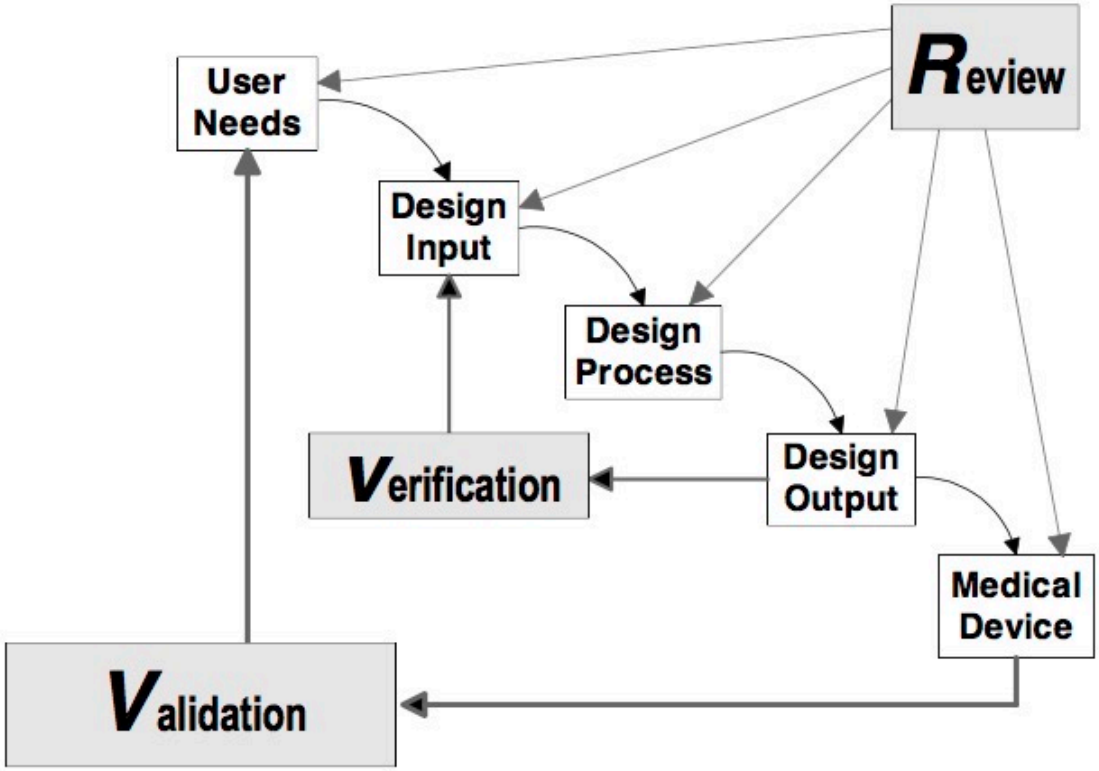
Design and development process shall ensure the devices are:

- safe to use
- simple to use as possible to prevent error
- reliable and ensure expected performance
- compliant with regulatory & ethical Standards

⇒ Well designed and well tested!

MD design and development – V-Model

V-Model

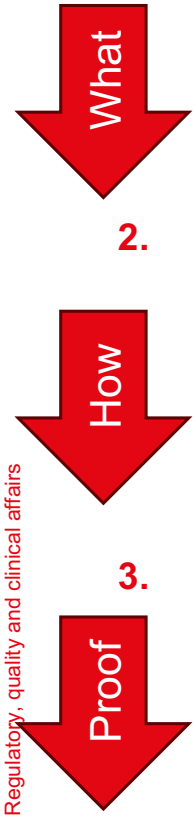


- FDA's Design Control Guidance for Medical Device Manufacturers (1997)* was among the first to introduce the "V-Model" for the development of medical device.
- The V-Model emerged in the 1980s and was later formalized in systems engineering. Widely adopted in military, aerospace, automotive, and medical industries, it ensures structured validation and verification.
- Organizations like NASA, FDA, and ISO integrated its principles into regulatory frameworks.

https://www.fda.gov/media/116573/download

MD design and development – V-Model

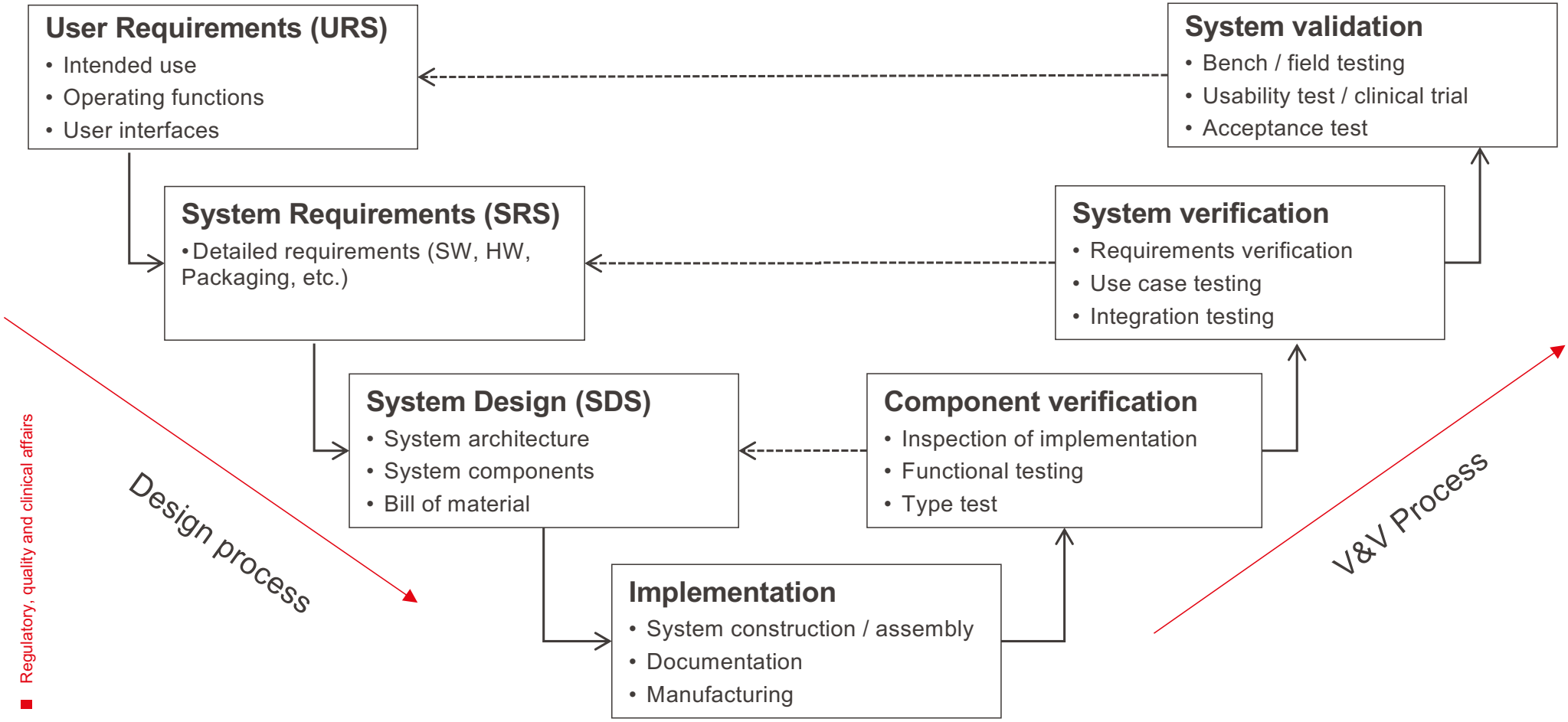
The design and development process may be structured around 3 meta-activities



1. **Identification of Design Inputs (Requirements Definition)**
   - Clearly definition of design input requirements to ensure the device meets user needs, regulatory standards, and functional expectations.
   - Requirements shall be be objective, measurable, and testable, covering aspects like performance, safety, usability, and regulatory constraints.
2. **Design and Development Planning**
   - Manufacturers must develop and maintain comprehensive design plans outlining responsibilities, timelines, and required resources.
   - Plans should be updated throughout development to reflect evolving requirements and progress.
   - Manufacturers are obligated to implement design control to ensure medical devices are developed in a systematic, traceable manner, integrating risk management and verification processes
3. **Design Verification, Validation, and Change Control**
   - Verification confirms that design outputs match the initial requirements through testing and analysis.
   - Validation ensures that the final product meets user needs and intended uses in real-world conditions.
   - Any design changes must be controlled, assessed, and documented to prevent unintended risks.

MD design and development – V-Model

The V-model as usually presented in the development lifecycle.



MD design and development – Design input

Design inputs

Requirements serve as a foundation for the development process, guiding design decisions, testing, and validation. They define what is needed to achieve **the intended purpose**.

Requirements are used to set the demonstration of the safety, performance and effectiveness of a system. They define what is needed to achieve **regulatory compliance.**

Requirements enable to:

- Define the goals and expectations for a product or system.
- Ensure all stakeholders have a shared understanding of objectives.
- Direct the design, development, and decision-making process.
- Provide measurable criteria to test if objectives are met.
- Minimize errors, misunderstandings, and redesigns.
- Ensure adherence to regulatory and industry standards.

MD design and development – Design input

Product Managers / Management

- Define product vision, market needs, and high-level requirements.

R&D Teams:

- Provide technical feasibility, innovation input, and development constraints.

Regulatory Affairs Specialists:

- Ensure compliance with regulations (e.g., FDA, EMA, ISO standards).

Quality Assurance Teams:

- Define requirements for testing, validation, and quality control.

Clinical Affairs Teams:

- Ensure the device meets clinical use cases and supports clinical trials.

Marketing and Sales Teams:

- Provide insights into customer preferences and competitive landscape.

Physicians:

- Define clinical needs, usability requirements, and patient outcome expectations.

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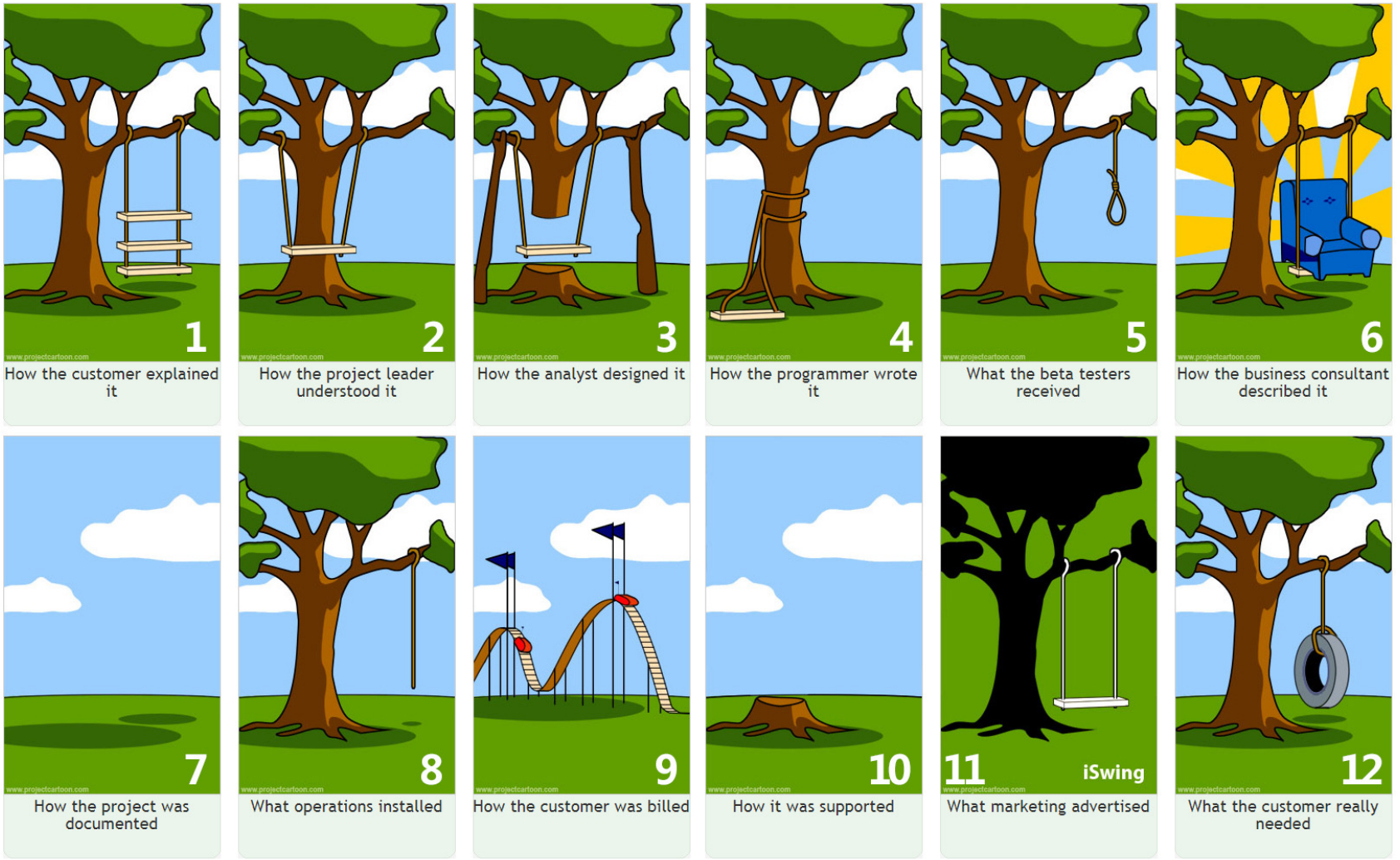
MD design and development – Design input

Design inputs



MD design and development – Design input

Multiple types of requirements

Design requirements

How is the device built

Usability requirements

How is the device used

Manufacturing requirements

How the device is manufactured

Test requirements

How the device is tested

Performance requirements

How the device performs

Safety Requirements

How the device ensures user safety

Maintenance Requirements

How the device is maintained

Functional Requirements

What the device must do

Usability requirements

How is the device used

Reliability Requirements

What is the probability of the device functioning without failure.

Environmental Requirements

In what condition the device must perform

Interface Requirements

How the device interacts with other systems, hardware, or software.

Regulatory and Compliance Requirements

What laws, standards, and industry regulations the device must adhere to

MD design and development – Design input

Design inputs

Examples of requirements for an electrode

URS#	REQUIREMENT	DESCRIPTION	TYPE
1.2.20	Biocompatibility-Acceptable release of materials in the brain	Under stimulation the lead shall release acceptable levels of chemicals (polymers, metals) in the brain.	must
1.2.25	Mechanical properties	Materials chosen shall withstand the mechanical stresses during transport and storage, and operation.	must

Examples of requirements for software medical device

5.1.11 Browser error message – REQ-136 / Shall / Usability

In case of a browser error, a message shall be displayed requesting to use a compatible browser. The compatible browsers shall be listed in the message (REQ-105).

5.2.28 Full Screen Mode REQ-149 / Shall / Usability

The app shall switch automatically in full screen mode to get rid of the tabs and use all available screen. the switch in full screen shall be when clicking the first “Continue” button.

MD design and development – Design output

A **design specification** is a structured document which serves as a blueprint for designers, engineers, and stakeholders, ensuring the final outcome meets user needs, technical constraints, and business goals. It includes details on materials, dimensions, functionalities, performance criteria, and compliance requirements, reducing ambiguity and minimizing risks.

Typical design outputs – i.e. design specifications:

Mechanical Specifications

- Drawing (Contact Layout Drawing, Electrode Assembly Drawing, Connector Interface Drawing, etc.)
- Component mechanical specification (casing specification, etc.)

Electrical Specification

- Electrical Schematic, EMC Shield specification, etc.

Packaging specification

- Packaging datasheet, Label specification, packaging sealing specification, etc.

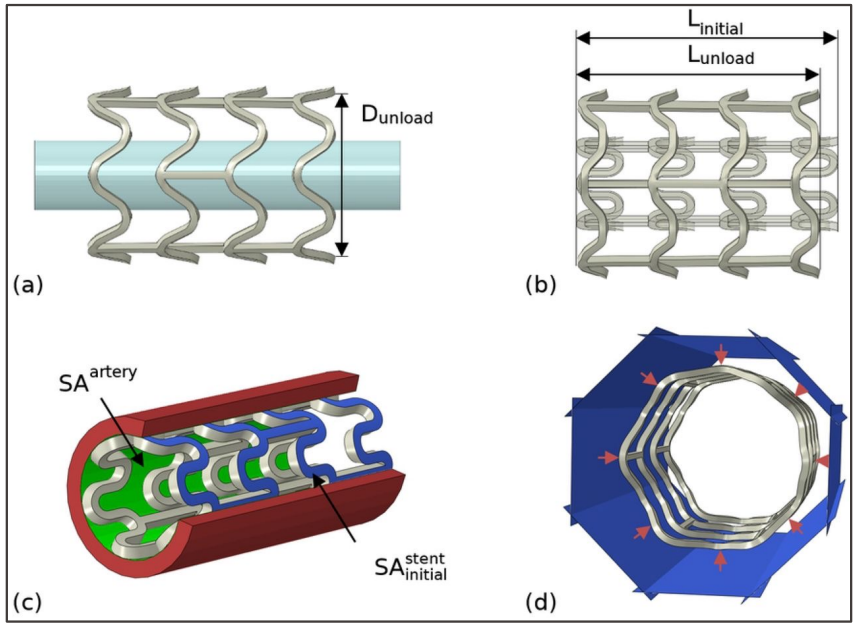
Components specification

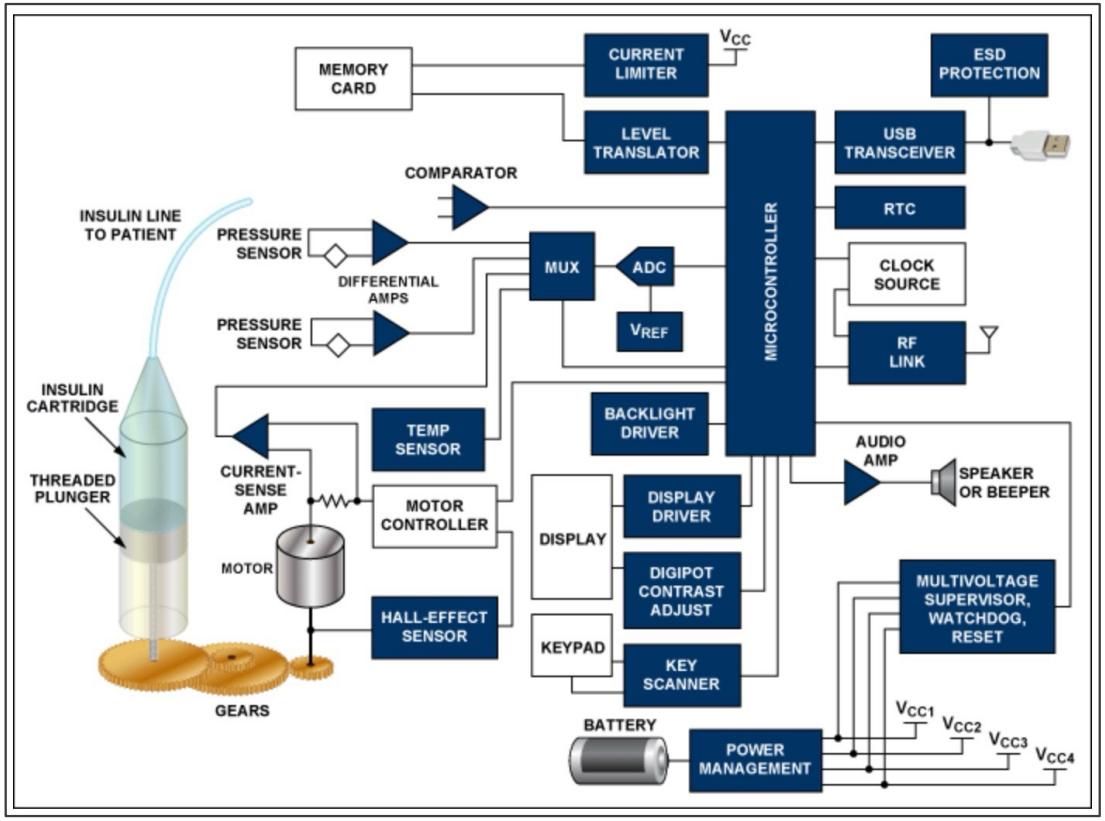
- Bill of material, component datasheet, incoming inspection specification

MD design and development – Design output

Design outputs

Example of design specifications for a stent





Functional block diagram of an insulin pump

MD design and development – Design outcome

The purpose of the design process is to translate user needs in specification for the conception and manufacturing of the device.

What is the need associated with the use of product

What is the product characteristic we want

How we implement it

ID	User Needs	Design Input	Design Output
1	The pump shall administer an accurate and **safe dosage** of insulin based on the user's prescribed needs to prevent hyperglycemia and hypoglycemia.	The pump shall be capable of delivering insulin doses ranging **from 0.5 to 200 units** per day, with an **accuracy of ±5%**, and **allow for user-specific dose adjustments**.	Software design specification (dose formula, instruction to electronic, etc.)
2			User interface specification (graphics, button, field, etc.)
3			Pump electronic specification (sensor, mechanic controls, etc.)

MD design and development – V & V

Verification and validation (V&V) activities ensure that a device, system, or software meets its requirements and functions correctly.

It plays a critical role in demonstrating a device's safety, reliability, and efficacy by providing objective evidence that it meets all required standards, technical, regulatory and user expectations.

Verification

Confirmation by examination and objective evidence that the specified requirements have been fulfilled

=> System functions (technical perspective), the system works as planned (i.e. dose accuracy)

Validation

Confirmation by examination and objective evidence that the specified intended use is consistently fulfilled

=> System achieves its purpose (user perspective), I can deliver the treatment (i.e. no hyperglycemia nor hypoglycemia)

MD design and development – V & V

Example of verification activities:

- Functional Testing: Testing the functionality of the device under expected conditions to verify that it works as intended.
- Software code reviews: review source code to identify bugs, improve quality, and ensure requirements are met.
- Packaging verification : verify the packaging characteristics are robust enough for the intended use.
- Sterility and Biocompatibility Testing: Ensuring that the device meets biocompatibility standards, if applicable (e.g., ISO 10993 for biocompatibility testing).
- Electrical testing: Verify the device is electrically safe, meet performance requirements, and protect patients and operators from electrical hazards

⇒ Activities to control that the device works as expected, it does what we expect .

MD design and development – V & V

Example of validation activities:

- Clinical Validation : conduct clinical trials or studies to validate the device's performance and safety in the intended patient population, ensuring it provides the intended benefits.
- Usability Validation : confirm the device is easy to use and can be operated safely and effectively by the intended users, through usability testing and human factors studies.
- Environmental Validation : Confirm the device can withstand environmental conditions like temperature, humidity, and vibration during storage, transport, and use.
- Packaging validation : verify the packaging effectively protects the device from damage during storage and transport.

⇒ Activities to control that the user can benefit from the use of the device

MD design and development – V & V

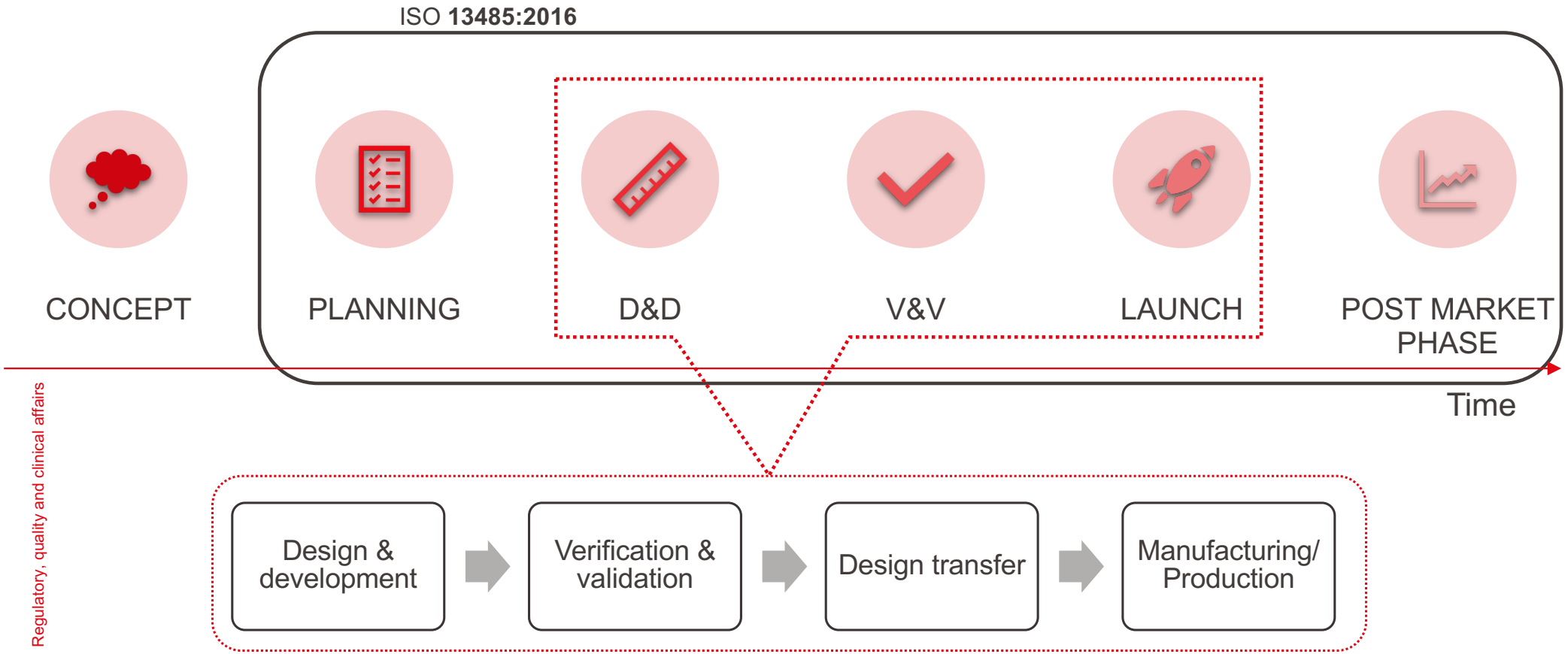
The purpose of the design process is to translate user needs in specification for the conception and manufacturing of the device.

ID	User Needs	Design Input	Design Output	Design Verification	Design Validation
1	The pump shall administer an accurate and safe dosage of insulin based on the user's prescribed needs to prevent hyperglycemia and hypoglycemia.	The pump shall be capable of delivering insulin doses ranging from 0.5 to 200 units per day, with an accuracy of ±5%, and allow for user-specific dose adjustments.	Software design specification	Software code review Software integration test	Clinical trial
2			Pump electronic specification	Functional testing	
3			User interface specification	Usability review	Usability study

MD design and development – Organisation and planning

Kim Rochat

Classical product development sequence



MD design and development – Organisation and planning

ISO 13485 - Quality management systems — Requirements for regulatory purposes

Provides a comprehensive QMS that organizations must meet to demonstrate their ability to provide medical devices and related services.

The chapter 7.3 of the ISO 13485 provides the following stage to follow:

- 7.3.1 General
- 7.3.2 Design and development planning
- 7.3.3 Design and development inputs
- 7.3.4 Design and development outputs
- 7.3.5 Design and development reviews
- 7.3.6 Design and development verification
- 7.3.7 Design and development validation
- 7.3.8 Design and development transfer
- 7.3.9 Control of design and development changes
- 7.3.10 Design and development files

MD design and development – Organisation and planning

Each clauses of ISO 13485, chapter 7.3 will provide specific activities to be performed

As an example:

7.3.2 Design and development planning

The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses.

During design and development planning, the organization shall document:

a) the design and development stages;

b) the review(s) needed at each design and development stage;

c) the verification, validation, and design transfer activities that are appropriate at each design and development stage;

d) the responsibilities and authorities for design and development;

e) the methods to ensure traceability of design and development outputs to design and development inputs;

f) the resources needed, including necessary competence of personnel.

MD design and development – Organisation and planning

STAGE	DESCRIPTION	ACTIVITIES
Stage 0	Concept definition	Definition of product objectives and intended use, establishment of the state of the art, IP Review, evaluation of technologies
Stage 1	Development Planning	Planning of activities, resources, documentation, setup of project organisation, identification of stakeholders Initial risk analysis
Stage 2	Design Inputs	Formalisation of user needs and requirements, Identification of regulatory requirements, Formalisation of technical requirements Risk analysis
Stage 3	Design Outputs	Conception of the device, development of design specifications, development of packaging specification, development of labelling and instruction for use, development of V&V Plan
Stage 4	Verification and Validation	Test plans, test protocols, test activities, reviews, studies (usability, clinical).
Stage 5	Production Transfer	Manufacturing processes implementation, selection and qualification of suppliers.
Stage 6	Regulatory Approval	Conformity assessment process
Stage 7	Commercialisation	Manufacturing ramp-up, Commercial Launch, Post Market Surveillance

MD design and development – in a nutshell

- Medical device design and development is a **systematic process** that ensures safety, effectiveness, and regulatory compliance while meeting user needs. Its purpose is to ensure only reliable devices are placed on the market. The process rely on effective traceability between design decisions, changes, verification and validation throughout the device lifecycle.

- **Verification activities** are critical to confirm the device meets its design specifications and provides sufficient level of reliability. It contributes to detect and eliminate defects early, they ensure consistency in performance across multiple units and operating conditions, it serve to demonstrate compliance with safety and functional requirements before regulatory submission.

- **Validation activities** ensures the device performs as intended in real-world conditions and achieves its clinical purpose safely and efficiently. They ensure the device can be used safely and efficiently by healthcare professionals and patients and serve to demonstrate the device's benefits outweigh potential risks in actual use.

Q&A