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Design and Development for Medical Devices: Navigating ISO 13485

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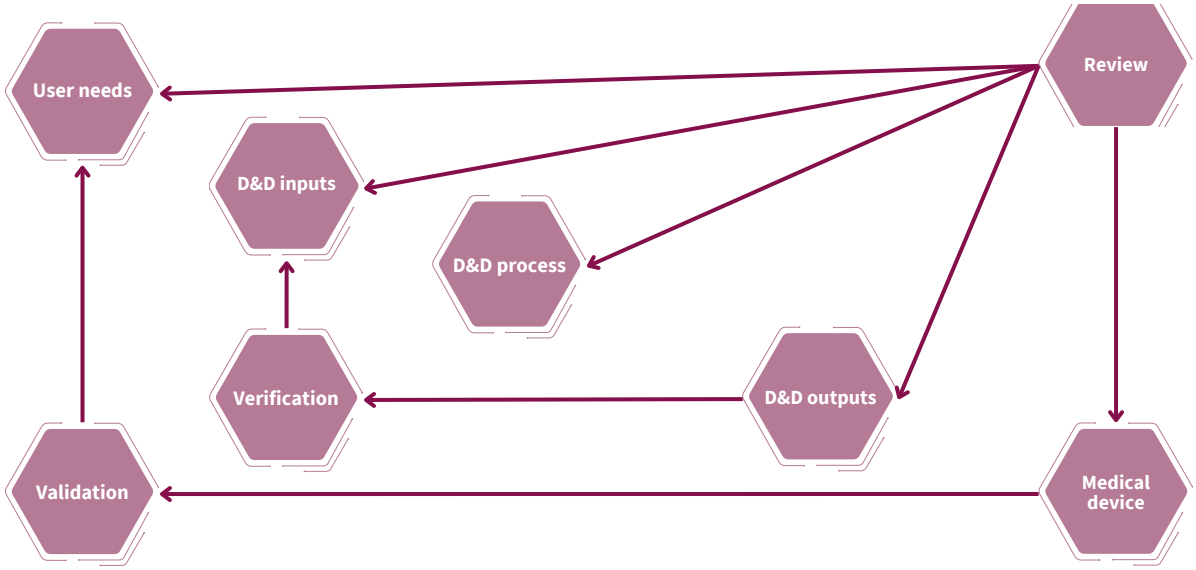
Key definitions

- **Design and development (D&D)**: A systematic process to ensure that medical devices meet applicable regulatory and customer requirements through planning, inputs, outputs, review, verification, validation, transfer, control of D&D changes, and D&D File
- **D&D File**: File containing records generated to demonstrate conformity to the requirements for D&D and records for D&D changes
- **Verification**: Confirmation by examination and objective evidence that the D&D outputs meet the D&D input requirements
- **Validation**: Confirmation by examination and provision of objective evidence that the resulting product is capable of meeting the user needs and the requirements for the specified application of the intended use

D&D requirements for medical devices are included in chapter 7. Product realization of the standard ISO 13485 Medical devices - Quality Management Systems - Requirements for regulatory purposes. In particular, section 7.3 describes all the requirements associated with D&D.

D&D procedure

The organization is required to document all D&D phases in a well-structured procedure. D&D is a set of processes that transforms requirements into specified characteristics of a medical device; being fundamental to achieve customer satisfaction.



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D&D planning

The organization shall plan and control the D&D of the medical device.
During this phase, the organization shall document:

- The D&D stages
- The review(s) needed at each D&D stage
- The verification, validation and design transfer activities that are appropriate at each D&D stage
- The responsibilities and authorities for D&D
- The methods to ensure traceability of D&D outputs to D&D inputs
- The resources needed, including necessary competence of personnel

Goal and objectives of the D&D of the product, major activities including risk management activities, the timeline of single activities and the whole project and the allocation of resources needed in each phase.

Proper planning can prevent unnecessary delays!

User needs

Identify and document the intended use and the indications for use of the medical device:

- Intended use is exactly what the device is used for, its general purpose or function.
- Indications of use describe the disease or condition, the situations, the reasons where and why the device is used, including users and target patient population.

As clear, precise and definitive as possible.

D&D inputs

Inputs relating to product requirements shall be determined and records maintained. This process implies turning the intended use and the indications for use of the device into a clear set of requirements, performance criteria and features of the device

This includes:

- Functional, performance, usability and safety requirements, according to the intended use
- Applicable regulatory requirements and standards
- Applicable output(s) of risk management
- As appropriate, information derived from previous similar designs
- Other requirements essential for D&D of the product and processes (i.e., environment, infrastructure, communications…)

For example: Specific materials, ease of Use, safety, performance, stability and shelf-life, supply, packaging, applicable legislation…

Requirements shall be complete, objective, unambiguous, measurable and not in conflict with each other. Include also industry standards and regulations!

The quality of D&D inputs is crucial for producing the right D&D outputs.

D&D outputs

Outputs shall be documented and provided in a form suitable for verification against the D&D inputs. D&D outputs shall:

- Meet the D&D inputs
- Provide appropriate information for purchasing, production and service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and correct use

For example: Description of the selected component parts and sub-assemblies, description of raw materials, diagrams and Technical Specifications, drawings, manufacturing process (including packaging, inspections, traceability and identification), environmental specifications…

Show how D&D Outputs relate and link to the D&D Inputs in a traceability matrix.

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D&D review

At suitable stages, systematic reviews of D&D shall be performed in accordance with planned and documented arrangements to:

- Evaluate the ability of the results of the D&D to meet requirements
- Identify and propose necessary actions to address detected problems.

Participants in this design review should be subject matter experts and representatives of functions concerned with the D&D stages being reviewed, as well as other specialist personnel if needed.

At the conclusion of each stage, it is necessary to check and record that the requirements are met.

D&D verification

D&D verification ensures that D&D outputs meet the specified D&D inputs. It is necessary to verify the device with the help of appropriate tests, procedures, inspections and analysis.

For example: Biocompatibility tests, performance tests, packaging verification, transport verification, sterilization, stability tests, supplier and components verification…

D&D validation

D&D validation is a step that comes after D&D verification and it is intended to ensure that the resulting device is capable of meeting the requirements for the specified application or intended use. D&D validation shall be conducted on representative product including initial production units or their equivalents; and shall be completed prior to release for use of the product to the customer.

For example: Clinical evaluation, usability evaluation…

D&D transfer

Document a procedure to transfer D&D outputs to manufacturing. This means that product development has made sure that the design can be implemented in production so that the device can be manufactured exactly as required.

To ensure that everything needed for production is ready and done.

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Control of D&D changes

Document a procedure to control D&D changes. It is necessary to determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the device and its intended use. Before implementation, changes should be reviewed (evaluation of the effect on constituent parts and product, risk management and product realization), verified, validated and approved.

D&D File

Maintain a D&D File for each medical device. The File may include or reference records to demonstrate conformity to the requirements for D&D, verification, validation, reviews, transfer and records for D&D changes.

The D&D file compiles everything: D&D activities, documentation, and records. If it is not documented, it did not happen!

D&D file (or DDF) and other regulations:

US FDA format	ISO 13485 format	MDR 2017/745 format
DHF - Design History File (21 CFR 820.30)	DDF - Design and Development File (clause 7.3.10)	TD - Technical Documentation (Annex II + Annex III)
DMR - Device Master Record (21 CFR 820.181)	MDF - Medical Device File (clause 4.2.3)	
DHR - Device History Record (21 CFR 820.184)		

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How can Asphalion help you?

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MedTech is the specialized division for Medical Device Regulatory Support within Asphalion.

Strategic Guidance
Development of comprehensive roadmaps and preparation of De Novo classification requests.

Facilitating FDA Submission Process
Assisting in compiling, organizing, and submitting the necessary documentation.

Engaging in FDA Meetings
Accompanying and representing the client in potential meetings with the FDA, ensuring all communications are effectively managed.

Post-Market Assistance
Providing ongoing support for compliance and regulatory requirements after the product launch.

Multidisciplinary team
Highly qualified personnel.

Adaptability and confidentiality

Tailored services

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