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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. It encompasses planning, inputs, outputs, reviews, verification, validation, transfer, control of D&D changes, and maintaining the 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.

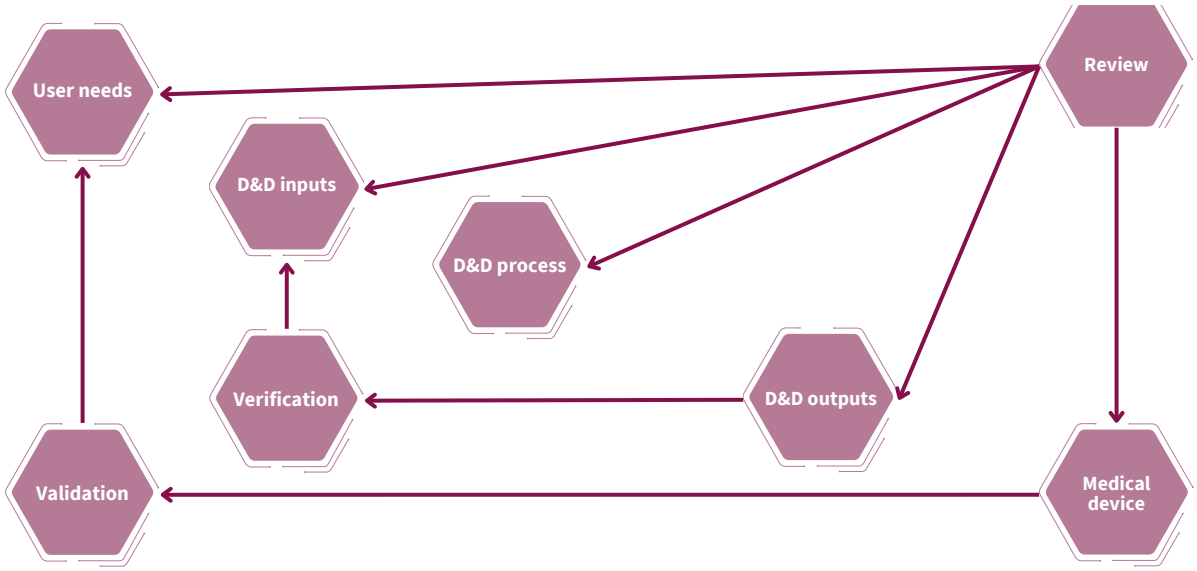
Verification: Confirmation by examination and objective evidence that the D&D outputs meet the D&D input requirements.

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 outlines all the requirements related to 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 transform requirements into specified characteristics of a medical device, playing a fundamental role in achieving 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, it 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.

The goals and objectives of the product's D&D, major activities (including risk management activities), the timeline for individual activities and the overall project, and the allocation of resources required at 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:

- The **intended use** refers to the general purpose or function of the device — specifically, what the device is designed to do.
- **Indications of use** describe the diseases, conditions, or clinical situations 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.

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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, etc.).

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

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, and so on.

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 appropriate stages, systematic reviews of D&D shall be performed in accordance with the planned and documented procedures 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 products, including initial production units or their equivalents, and must be completed prior to the product's release for customer use.

For example: Clinical evaluation, usability evaluation, etc.

D&D transfer

Document a procedure to transfer D&D outputs to manufacturing. This ensures that product development has verified the design's feasibility for production, enabling the device to be manufactured exactly as required.

Ensure that everything required for production is ready and completed

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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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info@asphalion.com

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Author

Koldo García de Acilu
Medical Device Consultant