WHAT IS DESIGN HISTORY FILE?

Design History File (DHF) means a compilation of records which describes the design history of a finished device. It is a summation record of all **design and development actions**, from start of development to transfer to manufacturing, including changes.

WHAT DO I NEED DHF FOR?

The purpose of establishing DHF is to support compliance with regulatory requirements.

DHF is a truly US term and fully defined in FDA 21 CFR 820.30. Each manufacturer shall establish and maintain a design history for each type of device.

The new 13485:2016 requires manufacturer to maintain a design and development file for each medical device type or medical device family. This file shall include, or reference record generated to demonstrate conformity to the requirements for design and development and record for design and development changes.

The following table compares the FDA requirements for Design Control to ISO 13485 clauses regarding Design and Development.

Design Controls FDA 820.30	Design and Development ISO 13485
(a) General	7.3.1 Design and Development Planning
(b) Design and Development	7.3.1 Design and Development Planning
(c) Design Input	7.3.2 Design and Development Inputs
(d) Design Output	7.3.3 Design and Development Outputs
(e) Design Review	7.3.4 Design and Development Review
(f) Design Verifications	7.3.5 Design and Development Verification
(g) Design Validation	7.3.6 Design and Development Validation
(h) Design Transfer	7.3.1 Design and Development Planning
(i) Design Changes	7.3.7 Control of Design and Development
(j) Design History File	No Referenced Materials

Both FDA Design Controls regulations and ISO 13485 Design and Development requirements expect you to keep documentation and records throughout the product development process.

The best way to demonstrate the linkages and the relationship between User Needs, Design Inputs, Design Outputs, Design Verifications and Design Validation is construct an Input-Output-Verifications-Validation Matrix (IOVV).

Is your DHF in compliance with the new MDR requirements?

According to the new Medical Device Regulation 2017/745, the technical documentation shall include information to allow the design stages applied to the device to be understood. It therefore includes the device's design, development, V&V (including clinical and performance validation) as well as its regulatory status within target markets.

This document shall be constantly updated to guarantee that "General Safety and Performance Requirements (GSPRs) are continuously fulfilled and that the benefits always outweigh the risks. The following inputs shall be considered for the file update:-

a) Regulatory changes
b) Design changes,
c) Latest Risk Analysis
d) Production process changes
e) Change in suppliers
f) Post Market Surveillance data
g) Post Market Clinical Follow-up
h) Audit results
i) Any other factors affecting the product performance, safety and regulatory requirements

What is the Typical Content of a DHF?

1. Purpose
2. Scope
3. Definitions
4. Responsibilities and Review Panel
5. Design and Development Process
6. Design History Documentation
    - 6.1. Project Proposal
    - 6.2. Project Development Plan
    - 6.3. Design Input Evaluation

6.4. Design Output Evaluation
6.5. Input-Output Matrix
6.6. Design Transfer Evaluation
7. Location of Documents
8. Control of Documents
9. Maintenance of Documents
10. Verification and Validation Test Reports

What is the relationship between DHF, DMR and Technical File?

DHF describes design traceability while DMR illustrates purchasing and production traceability. Technical File represents the entirety of documents describing a device.

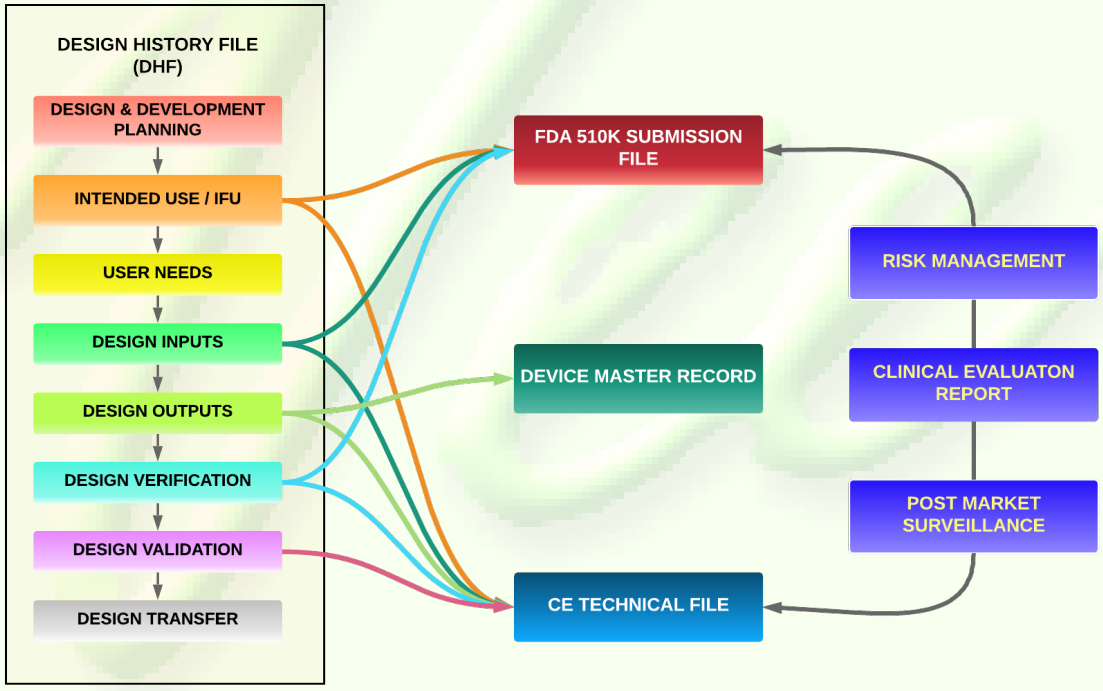

Figure adapted from Greenlight Guru and Medical Device Academy

WHAT DOES AN IOVV MATRIX LOOK LIKE?

User Needs	Design Input	Design Output	Verification/ Validation Criteria	Verification/Validation Method	Verification/ Validation Evidence	Responsible Department
IFU						
Physical Properties						
Chemical Properties						
Product Performance						
Product Safety						
Product Sterility						
Product Stability						
Marking & Labeling						
Usability						

References:

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