UNIK PARTNER

Summary

D:s in development

When developing products in life science there are four abbreviations that are hard to remember the meaning of – DHF, DMR, DHR and DMR.

DHF (Design History File) – how was it developed?
DMR (Device Master Record) - how was it built and tested?
DHR (Device History Record) - how was it produced?
DMF (Drug Master File) – disclosed information reference.

DHF (Design History File)

This document contains (or refer) to all records needed to demonstrate that the design was developed according to the approved design plan and fulfills the requirements.

The records that should be in the DHF follows:

- User needs and design inputs defined at the start of the project.
- Design outputs that was generated building the device.
- Design verification and validation protocols and reports.
- Design reviews associated with user needs, design inputs and outputs, and design verification and validation protocols.
- Design changes.
- All materials relevant to design transfer into manufacturing

DMR (Device Master Record)

This document includes all the information needed to produce a product.

The document should include or refer to the following material:

- Device specifications (drawings, composition, formulation, component specifications, and software specifications).
- Production process specifications (equipment specifications, production methods, production procedures, and production environment specifications).
- Quality assurance procedures and specifications (acceptance criteria and the quality assurance equipment to be used).
- Packaging and labeling specifications (methods and processes used).
- Installation, maintenance, and servicing procedures and methods.

Summary

DHR (Device History Record)

This record stores data of how the device was manufactured.

The document should include or refer to the following material:

- Dates of manufacture.
- Quantity manufactured and released for distribution.
- The acceptance records (demonstrate the device is manufactured in accordance with the DMR).
- Label and labeling used for each production unit.
- Device identification number

DMF (Drug Master File)

A file provided, by a pharmaceutical manufacturer, to the appropriate regulatory authority in the intended drug market.

Usually, the DMF includes detailed information about:

- Facilities
- Processes
- Articles

used in the manufacturing, processing, packaging, and storing of human drug products.
The file is confidential and allows other parties to reference material without disclosing DMF contents to those parties.