PD233: Design of Biomedical Devices and Systems

(Lecture-5 Design Documentation)

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Course Website:
http://cpdm.iisc.ac.in/utsaah/courses/

FDA CFR 21

In United States the requirements of Documentation are mandated by Title 21 of *Code of Federal Regulations (CFR)* for both drugs and medical devices.

- **Volume 1: Parts 1–99 (FDA, General)**
- **Volume 2: Parts 100–169 (FDA, Food for Human Consumption)**
- **Volume 3: Parts 170–199 (FDA, Food for Human Consumption)**
- **Volume 4: Parts 200–299 (FDA, Drugs: General)**
- **Volume 5: Parts 300–499 (FDA, Drugs for Human Use)**
- **Volume 6: Parts 500–599 (FDA, Animal Drugs, Feeds and Related Products)**
- **Volume 7: Parts 600–799 (FDA, Biologics; Cosmetics)**
- **Volume 8: Parts 800–1299 (FDA, Medical Devices)**
- **Volume 9: Parts 1300–End (DEA and Office of National Drug Control Policy)**

for example

21 CFR part 820: defines medical device quality system (QS) regulation;

Sec 820.5

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

EU: MDD Annex VII

2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices the period shall be at least 15 years after the last product has been manufactured.

Indian Medical Device Rule 2017: Fifth Schedule

Quality Management system MDs

4.2 Documentation requirements.-

4.2.1 General

The quality management system documentation shall include;-

(a) documented statements of a quality policy and quality objectives;

(b) a quality manual;

(c) documented procedures required by this schedule;

(d) documents needed by the manufacturer to ensure the effective planning, operation and control of its processes;

(e) records required by this Schedule, and

where this Schedule specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained.

ISO 13485: 2016

4.2 Documentation requirements

4.2.1 General

The quality management system documentation (see 4.2.4) shall include:

a) documented statements of a quality policy and quality objectives;

b) a quality manual;

c) documented procedures and records required by this International Standard;

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;

e) other documentation specified by applicable regulatory requirements.

4.2.2 Quality manual

The organization shall document a quality manual that includes:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application;

b) the documented procedures for the quality management system, or reference to them;

c) a description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

4.2.3 Medical device file

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

Documentation Requirements

- Maintained by manufacturer
- Auditable by FDA or equivalent authority
- They must be legible and stored so as to minimize deterioration and to prevent loss
- Those stored digitally must be backed up and have a disaster plan in effect
- Can be deemed as confidential
- To be maintained for expected life time of the product (but not less than 2 year)

Documents

Information used to support an effective and efficient organizational operation.

Documents are created as a part of your planning

Need to be reviewed, updated and approved – i.e. document control.

- Business proposal
- Product specification
- Design specification
- Software quality assurance plan (SQAP) (where applicable)
- Software requirements specification (SRS) (where applicable)
- Software design description (SDD) (where applicable)

Records

Records are evidence of activities in past.

Records are facts and should not change, new records can be added.

Four types of records in context of medical devices:

1. Design History File (DHF)
2. Device Master Record (DMR)
3. Device History Record (DHR)
4. Technical Documentation File (TDF)

Documents

Business Proposal

Purpose: to identify and document market needs, market potential, the proposed product and product alternatives, risks and unknowns, and potential financial benefits.

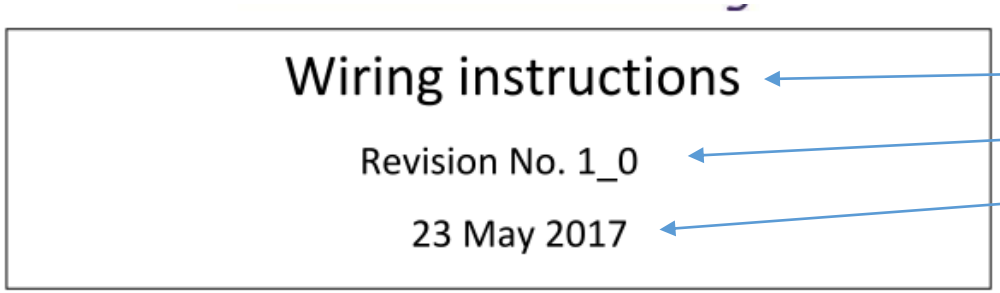
The business proposal usually contains:

- Project overview, objectives, major milestones, schedule
- Market need and market potential
- Product proposal
- Strategic fit
- Risk analysis and research plan
- Economic analysis
- Recommendation to form a core project team
- Supporting documentation

Product Specification

- First step in realizing a product idea into a approved product development effort.
- It specifies ***what the product will do, how it will do it,*** and ***how reliable*** it will be. To be effective, it must be as precise as possible.
- The product specification ***should be a controlled document***, i.e., subject to revision level control, so that any changes that arise are subjected to review and approval before implementation.

Controlled Document



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Revision No.	Summary of changes	Date of Release
1.0	Initial Release	23 May 2017

Product Specifications

The specification is a detailed review of the proposed product and includes

- Type of product
- Market it addresses
- Technology to be used
- Function of the product
- Product parameters necessary to function effectively
- Accuracy requirements
- Tolerances necessary for function
- Anticipated environment for the device
- Cautions for anticipated misuse
- Safety issues
- Human factors issues
- Anticipated life of the product
- Reliability goal
- Requirements from applicable domestic or international standards

Product Specifications

- ***Product specification are derived by agreement of multiple stakeholders:*** marketing, design engineering, manufacturing, customer service, reliability assurance, quality assurance, and regulatory affairs
- ***Each requirement should be identified with some form of notation***, such as brackets and a number.

  Example:

  5.3.1 Analog to Digital Converter

  The output of the analog to digital converter must be between X and Y [1].

This requirement can be later referred to as 5.3.1-1

Design Specifications

- The design specification is a document, which is derived from the product specification.

The requirements found in the product specification are partitioned and distilled down into specific design requirements ***for each subassembly.***

Design Specification

The design specification should address the following areas for each subsystem:

- Reliability budget
- Service strategy
- Manufacturing strategy
- Hazard consideration
- Environmental constraints
- Safety
- Cost budgets
- Standards requirements
- Size and packaging
- Power budget
- Heat generation budget
- Industrial design/human factors
- Controls/adjustments
- Material compatibility

Design Specifications

All electrical and mechanical ***inputs and outputs*** and their ***corresponding limits*** under all operating modes must be defined.

As in the product specification, the requirements in the ***design specification should be identified by a notation*** such as a bracket and numbers.

Other Controlled Documents

- Software quality assurance plan (SQAP)
- Software requirements specification (SRS)
- Software design description (SDD)

Reference: Chapter 5, King & Fries, Design of Biomedical Devices and Systems

Records for Medical Device

1. Design History File (DHF)
2. Device Master Record (DMR)
3. Device History Record (DHR)
4. Technical Documentation File (TDF)

Design history file (DHF)

- DHF is a compilation of records, which describes the ***design history*** of a finished device.
- It covers the design activities used to develop the device, accessories, major components, labeling, packaging, and production processes.
- The DHF contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plans and the requirements of the quality system regulation.
- CFR 21 820.30(j) requires that each manufacturer establish and maintain a DHF for each type of device.

Design history file (DHF)

The ***design plans and subsequent updates*** should be part of the DHF.

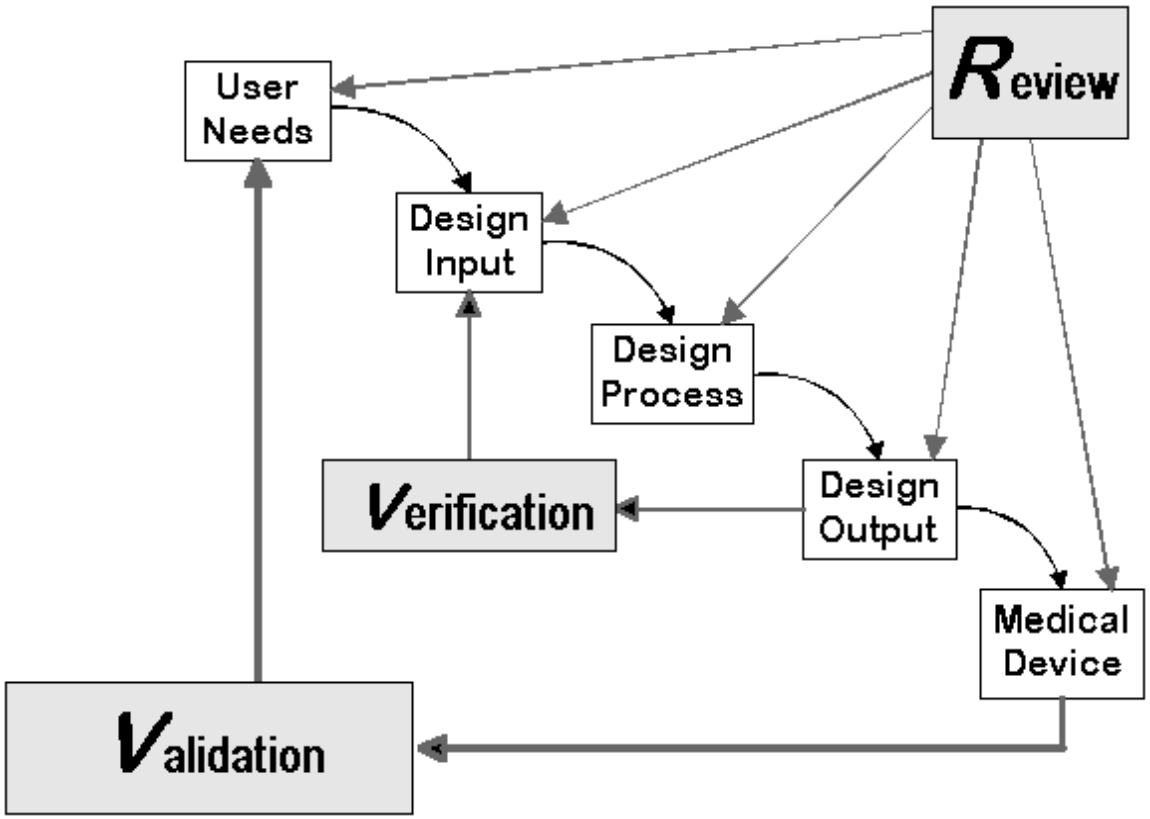
In addition, the Quality System (QS) regulation specifically requires that

- ***Results of a design review***, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the DHF.
- ***Design verification shall confirm that the design output meets the design input requirements***. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

Design history file (DHF)

Typical documents that may be in, or referenced in, a DHF include

- Design plans
- Design review meeting information
- Sketches
- Drawings
- Procedures
- Photos
- Engineering notebooks
- Component qualification information
- Biocompatibility (verification) protocols and data
- Design review notes
- Verification protocols and data for evaluating prototypes
- Validation protocols and data for initial finished devices
- Contractor/consultants information
- Product Documentation
- Parts of design output/DMR documents that show plans were followed
- Parts of design output/DMR documents that show specifications were met



Medical device design process as specified US- FDA requirements (source http://fda.gov)

Design history file (DHF)

- Manufacture of the device are beneficiary of DHF
- When problems occur during redesign and for new designs, the DHF has the institutional memory of previous design activities
- The DHF contains valuable verification and validation protocols that are not in DMR.

Device master record (DMR)

DMR is a compilation of those records containing the ***specifications and procedures for a finished device***.

DRM should include or refer to location of information about:

- ***Device specifications*** including appropriate drawings, composition, formulation, component, specifications, and software specifications
- ***Production process specifications*** including the appropriate equipment specifications, production methods, production procedures, and production environment specifications
- ***Quality assurance procedures and specifications*** including acceptance criteria and the quality assurance equipment used
- ***Packaging and labeling*** specifications, including methods and processed used
- ***Installation, maintenance, and servicing*** procedures and methods

Device history record (DHR)

DHR is the ***actual production records*** for a particular device.

It show the ***processes, tests, rework, etc.*** that the device went through.

The DHR should include or refer to the location of the following information:

- Dates of manufacture
- Quantity manufactured
- Quantity released for distribution
- Acceptance records which demonstrate the device is manufactured in accordance with the DMR
- Primary identification label and labeling used for each production unit
- Any device identification and control numbers used

Technical Documentation File (TDF)

TDF contains all the relevant design data by means of which the product can be ***demonstrated to satisfy the essential safety requirements***.

It must include:

- General description of the product, including any planned variants.
- Design drawings, methods of manufacture envisaged and diagrams of components, subassemblies, circuits, etc.
- Descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the operations of the product.
- ***Results of the risk analysis*** and a list of applicable standards applied.
- For products placed on the market in a sterile condition, a description of the method is used.
- ***Results of the design calculations and of the inspections carried out.***
- ***Test reports and, where appropriate, clinical data.***
- Labels and instructions for use.

Quiz

	DHF	DMR	DHR	TDF
Clinical Trial Information				
Project Plans				
Design Specification				
Design Validation Plans				
Product Specification				
Sales order report				
Shipping report				
Risk analysis				
Tooling specs				
Installation Instructions				