

DESIGN, TESTING, AND MANUFACTURING OF MEDICAL DEVICES

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Preamble

This document provides an overview of Design, Testing, and Manufacturing of Medical Devices

The Design process consists of 5 phases.

Phase 1 (Concept)

Phase 2 (Design Input)

Phase 3 (Design Implementation)

Phase 4 (Product Validation)

Phase 5 (Production)

Concept Phase

In this phase, the manufacturer needs to assess the market and business opportunity of the new medical device. This involves understanding the needs of the customer. It needs an assessment of the value of the device. The factors to be considered include improvement in patient care, lowering the cost of the existing procedure. Other factors such as the new device being marketed as a replacement or an additional device need to be considered.

Design Input Phase

In this phase it is assessed how the device will be designed and delivered. Applicable regulatory and voluntary standards will have to be considered. This includes the intended use and indications for use in the clinical environment. The hazards and risks will have to be considered during the design, testing or labeling of the device. The specifications of the device will have to be developed in clear, testable, and unambiguous terms.

Design Implementation

This phase includes design architecture which divides the design into manageable, testable and maintainable subsystems. Other steps include the development and documentation of the manufacturing processes, vendor supply selection, verification and Failure Modes and Effects Analysis.

Product Validation

In this phase the design is transitioned into production. The production of pilot units is started using the approved manufacturing processes. The design is validated in actual or simulated end user conditions. Reliability testing is performed and the Design History File and Master Record are completed.

Production

This phase involves post market surveillance which includes safety and effectiveness verification and meeting customer expectations. During the field reliability monitoring feedback is received for design improvements. Also life cycle management is conducted.

References

- Design Control Guidance for Medical Device Manufacturing, FDA Rockville MD
- FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, Kimberly A. Trautman, ASQC Quality Press, Milwaukee Wisc
- Reliable Design of Medical Devices, Second Ed. Richard Fries, Taylor and Francis, Boca Raton FL.

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