

Design Control Process

Design Control Process consists of out of 6 Design Control Phases. All together these phases are the foundation of a structured design and development as well as for the life cycle of a Medical Device. The successful completion of each individual phase marks progress toward completing the Design and Development Plan for a new Medical Device (or a change to the design of an existing Product).

Phase 1	Design and Development Planning
Phase 2	Design Inputs
Phase 3	Design Outputs
Phase 4	Design Verification
Phase 5	Design Validation
Phase 6	Design Transfer

Table 1: Design Control Phases

Each Design Control Phase has a defined end point with specific pre-planned exit criteria. One phase may begin prior to completion of the previous phase; however, each phase must be completed with a review and approval by the Design Review Committee.

The initiation of subsequent phase activities prior to overall completion of the current phase shall be approved by the Design Review Committee and COMPANY Management.

Objectives are clearly defined and a team is formed to develop the requirements specifications. The goal is to provide a Medical Device that provides user satisfaction at an acceptable price that enables a satisfactory return on investment for COMPANY and ensures that the Product is producible, verifiable, and controllable under the proposed production, installation, operating and servicing conditions.

7.2 Design and Development Planning

The main purpose of the initial phase of the development is to generate a Design and Development project Plan. This plan consists of the following major areas:

- Goals and objectives of the design and development program
- Delineation of organization responsibilities, including internal and external resources
- Identification of project teams and the interfaces between such teams
- Identification of the major tasks, deliverables, budget and schedule
- Identification of Risk Analysis activities and timeframes, and
- Identification of major Design Reviews and decision points

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