

**Design Control Guidance
For
Medical Device Manufacturers**

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Overview

- Background
- Content of GHTF Guidance Document
 - Concepts and Guidance
 - Highlights & examples
 - Link to 21 CFR Part 820
 - Link to ISO 13485:1996 and ISO 13485:2003
- Inclusion in ISO TR 14969:2003



Background

- Document dated September 11, 1997
- Published as Study Group 3 Final Document
June 29, 1999
- GHTF.SG3.N99-9
- WWW.GHTF.ORG
 - .pdf version available



Background

- Introduction
- Section A. General
- Section B. Design and Development Planning
- Section C. Design Input
- Section D. Design Output
- Section E. Design Review
- Section F. Design Verification
- Section G. Design Validation
- Section H. Design Transfer
- Section I. Design Changes
- Section J. Design History File



Introduction

Purpose

- assist manufacturers understand QS design control requirements
 - “..interrelated set of practices and procedures ..incorporated into the design and development process.”
- General guidance - can not be used to demonstrate compliance with QS requirements
- provides practical explanations and examples of design control principles
- Manufacturers should reference technology-specific guidance for their particular situation



Introduction

Scope

- Guidance applies to design of devices as well as associated manufacturing processes
- Each section of guidance cross-referenced to ISO 13485:1996 and the US FDA QSR, 21 CFR Part 820



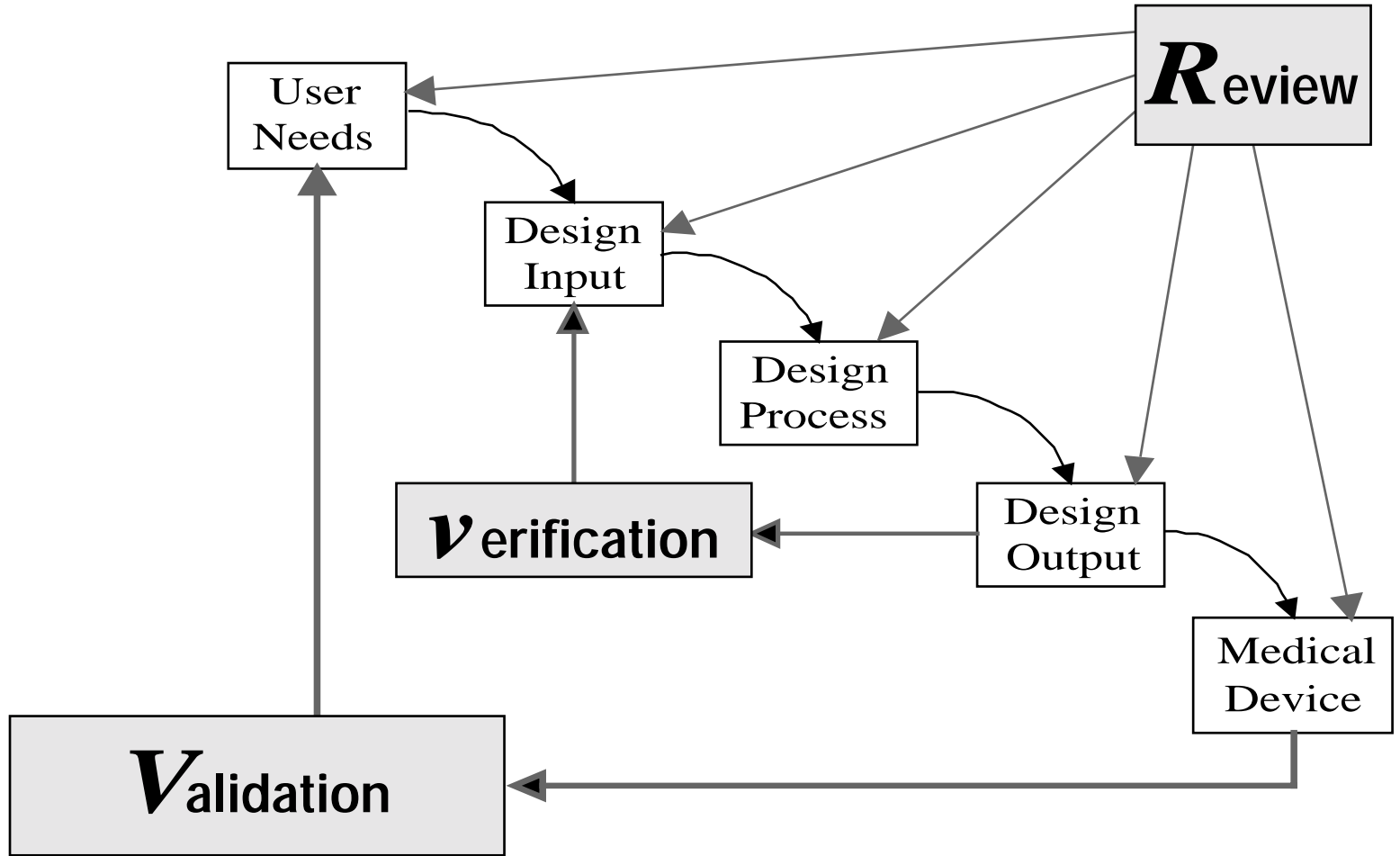
Introduction

Application of Design Controls

- Simple model - “water fall”
 - Useful for introducing concept of design control
 - Limited in practice
- Practical model – “concurrent engineering”
 - More representative of design process used in industry
 - Involvement of production and service personnel throughout the design process



Waterfall Model



Section A. General

- Cross references
 - Section 4.4.1 of ISO 13485:1996
 - Section 7.3.1 of ISO 13485:2003
 - QSR § 820.30(a)
- States that senior management (SM) is responsible for establishing a design and development plan
- Gives a list of potential internal policies that SM should ensure are established
 - Assessing new product ideas
 - Training of design managers & staff
 - Use of consultants
 - Evaluation of the design process
 - etc.



Section B. Design and Development Planning

- Cross references
 - Section 4.4.2 & 4.4.3 of ISO 13485:1996
 - Section 7.3.1 of ISO 13485:2003
 - QSR § 820.30(b)
- Planning is needed to ensure that design process is appropriately controlled and objectives are met
- Possible things to address in plan
 - Goals & objective
 - Organizational responsibility
 - Major tasks to be undertaken, deliverables, & responsible party
 - Major review & decision points
 - etc.
- Extent of plan related to size of the organization as well as size and complexity of product



Section C. Design Input

- Cross references
 - Section 4.4.4 of ISO 13485:1996
 - Section 7.2.1 & 7.3.2 of ISO 13485:2003
 - QSR § 820.30(c)
- Physical and performance requirements of a device that are used as a basis for device design
 - Starting point for product design
 - Functional, performance & interface
 - Reviewed for adequacy
- Product developer(s) responsible for translating user and/or patient needs into requirements that can be validated
- Potential problems
 - Difference in terminology (medical vs. engineering terms)
 - Incorrect assumptions
 - Determining scope and level of detail of requirements



Section D. Design Output

- Cross references
 - Section 4.4.5 of ISO 13485:1996
 - Section 7.3.3 of ISO 13485:2003
 - QSR § 820.30(d)
- Result of a design effort at each design phase and at the end of the total design effort
 - Forms basis of device master record (DMR)
 - Consists of device, packaging, labelling and DMR
- Expressed in terms that allows for assessment of conformance to design input requirements
 - Could be block diagram, flow chart, system or sub-system design specification



Section E. Design Review

- Cross references
 - Section 4.4.6 of ISO 13485:1996
 - Section 7.3.4 of ISO 13485:2003
 - QSR § 820.30(e)
- Documented, comprehensive, systematic examination of a design to :
 - Evaluate adequacy of the design requirements
 - Evaluate capability of the design to meet requirements
 - Identify problems
- Intent is to detect problems early
- Conducted at end of each phase and important milestones in the design process
- Performed by competent reviewers



Section F. Design Verification

- Cross references
 - Section 4.4.7 of ISO 13485:1996
 - Section 7.3.5 of ISO 13485:2003
 - QSR § 820.30(f)
- Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled
- Conducted at all stages and levels of device design
- Involves tests, inspections and analyses
 - Failure mode and effects analysis
 - Package integrity tests
 - Biocompatibility testing of materials
 - etc.



Section G. Design Validation

- Cross references
 - Section 4.4.8 of ISO 13485:1996
 - Section 7.3.6 of ISO 13485:2003
 - QSR § 820.30(g)
- assure that the design will conform with user needs and intended use(s), given expected variations in components, materials, manufacturing processes and the use environment
- Planning for validation should begin early in the design process
 - performance characteristics identified
 - Validation methods and acceptance criteria established
- Clinical evaluation performed



Section H. Design Transfer

- Cross references
 - Section 4.2.3 (c) of ISO 13485:1996
 - Section 7.3.6 of ISO 13485:2003
 - QSR § 820.30(h)
- Production specifications must ensure that manufactured devices are repeatedly and reliably produced within product and process capabilities
- Procedures for design transfer should ensure that :
 - design and development procedures include a qualitative assessment of the completeness and adequacy of the production specifications
 - all documents and articles which constitute the production specifications are reviewed and approved
 - only approved specifications are used to manufacture production devices



Section I. Design Changes

- Cross references
 - Section 4.4.9 of ISO 13485:1996
 - Section 7.3.7 of ISO 13485:2003
 - QSR § 820.30(i)
- Two main elements of design change
 - Document control (status & revision)
 - Change control (recording deficiencies and corrective actions)
- Multi-person projects call for special attention to be paid to coordination and communication of design changes



Section J. Design History File

- Cross references
 - Section 4.16 of ISO 13485:1996
 - Section 4.2.4 of ISO 13485:2003
 - QSR § 820.30(j)
- A means a compilation of records which describe the design history of a finished device
 - Every section of the design control requirements specifies information which should be recorded
 - No requirement on the location or organization of DHF
- No specific requirement found in ISO 13485
- US FDA QSR requirement



Future

- Study Group 3 reviewing existing document with the intent:
 - of verifying the ISO 13485:200x references
 - drafting a new section on design changes that occur following the launch of a design
- Points to consider include how the impact of corrective action & preventive action, nonconforming product, process validation experience, etc. influence the design process



End

Thank You



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