Quality System: Design Control Procedure - Appendix

CORP Medical Products

Various details have been removed, indicated by "[…]"

1. Overview

1.1. Objective

This document provides supplemental information for the CORP Design Control Procedure for Project Change Requests (PCR), in order to help understand the procedure as well as the rationale behind the procedure.

1.2. Scope

This is not a required procedure. This is only supplemental information pertaining to the CORP Design Control Procedure for PCRs.

1.3. Responsibility

This document shall be maintained by CORP Management personnel.

This document shall be reviewed as required by any CORP personnel involved with PCRs.

1.4. Procedure and Outputs

The following sections provide supplemental information about the CORP Design Control Procedure for PCRs to help in understanding its purpose, day-to-day use, and the rationale behind it. Text sections not marked as CORP Specific were paraphrased or extracted from FDA regulations as listed in the FDA Information section.

Sections that follow

1.5. Definitions

FDA Definitions

DCP	Document Change Procedures
DHF	Design History File
DMR	Device Master Record

CORP Definitions

RDRC	CORP Design Review Committee (MGMT personnel)

MGMT	Person(s) in management position
PP	Point Person
TAGSYS	System for tying all code and document versions to SCR state
SCR	Software Change Request (this is really a Product Change Request, but for historical reasons, we continue to call it an SCR).

1.6. References

CORP Quality System: Design Control Standard Operating Procedure (CORP.820.30.sop.doc)

CORP Quality System: Design Control Procedure Appendix (CORP.820.30.app.txt)

CORP Quality System: Design Control Procedure Tools (CORP.820.30.tools.txt)

CORP Quality System: Introductory Presentation (CORP.820.30.intro.ppt)

CORP Quality System WEB SCR Tool

2. FDA Information Sources

Following is the primary reference for the Design Controls guidelines.

- **[…]**

Following is another (simpler) view of the Design Controls, which is one section of the "Medical Device Quality Systems Manual, and is also referenced from the "Medical Device Quality Systems Manual: A Small Entity Compliance Guide". This seems to try to condense much of what the previous document says. Both were used in designing our procedures.

- **[…]**

Following is a document with one section of particular interest, titled Flexibility of the GMP (GMP stands for Good Manufacturing Practice).

- **[…]**

Information on the entire Device Quality Systems Manual, of which the Design Controls are just one part, exists at:

- **[…]**

3. Big Picture of the FDA Requirements:

3.1. Scope of 820

DC Indicates what we are addressing in our Design Control procedure.

- Code of Federal Regulations Title 21 - Food and Drugs Revised April 1, 2002:
- Part 820 - Quality system regulation
- Subpart A—General Provisions
  - 820.1 - Scope.

  - 820.3 - Definitions.
  - 820.5 - Quality system.
- Subpart B—Quality System Requirements
  - 820.20 - Management responsibility.
  - 820.22 - Quality audit.
  - 820.25 - Personnel.
- Subpart C—Design Controls **DC**
  - 820.30 - Design controls.
- Subpart D—Document Controls
  - 820.40 - Document controls.
- Subpart E—Purchasing Controls
  - 820.50 - Purchasing controls.
- Subpart F—Identification and Traceability
  - 820.60 - Identification.
  - 820.65 - Traceability.
- Subpart G—Production and Process Controls
  - 820.70 - Production and process controls.
  - 820.72 - Inspection, measuring, and test equipment.
  - 820.75 - Process validation.
- Subpart H—Acceptance Activities
  - 820.80 - Receiving, in-process, and finished device acceptance.
  - 820.86 - Acceptance status.
- Subpart I—Nonconforming Product
  - 820.90 - Nonconforming product.
- Subpart J—Corrective and Preventive Action
  - 820.100 - Corrective and preventive action.
- Subpart K—Labeling and Packaging Control
  - 820.120 - Device labeling.
  - 820.130 - Device packaging.
- Subpart L—Handling, Storage, Distribution, and Installation
  - 820.140 - Handling.
  - 820.150 - Storage.
  - 820.160 - Distribution.
  - 820.170 - Installation.
- Subpart M—Records
  - 820.180 - General requirements.
  - 820.181 - Device master record.
  - 820.184 - Device history record.
  - 820.186 - Quality system record.
  - 820.198 - Complaint files.
- Subpart N—Servicing
  - 820.200 - Servicing.
- Subpart O—Statistical Techniques
  - 820.250 - Statistical techniques.

3.2. Good Manufacturing Practice

Good Manufacturing Practice (GMP) Requirements Quality System (QS).

Regulation Information:

- FDA Talk Paper Announcing the GMP Final Rule
- The Good Manufacturing Practice (GMP) (also known as the Quality System Regulation) Final Rule as published in the Federal Register
- Design Controls
  - Design Control Guidance for Medical Device Manufacturers
    - See below for contents
- Human Factors
  - Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management
  - Do It By Design: An Introduction to Human Factors in Medical Devices
  - Human Factors Implications of the New GMP Rule
- Other Guidance Information
  - Medical Device Quality Systems Manual: A Small Entity Compliance Guide
    - See below for contents
  - General Principles of Software Validation (draft) Guidance for Industry
  - Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems
  - QSIT Inspection Handbook
  - Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems
  - Guidance on Quality System Regulation Information for Various PreMarket Submissions
- Related Information
  - GMP/QS Workshops with CDRH Participation Text

3.3. Design Control Guidance

Design Control Guidance for Medical Device Manufacturers. This guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001:

- FOREWORD
- PREFACE
- ACKNOWLEDGEMENT
- TABLE OF CONTENTS
- 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

3.4. Medical Device Quality Systems Manual

Medical Device Quality Systems Manual: A Small Entity Compliance Guide First Edition (Supersedes the Medical Device Good Manufacturing Practices [GMP] Manual):

1. The Quality System Regulation
2. Quality Systems
3. Design Controls **** THIS IS 820.30, what we have implemented ****
4. Process Validation
5. Personnel
6. Buildings and Environment
7. Equipment and Calibration
8. Device Master Record
9. Document and Change Control
10. Purchasing and Acceptance Activities
11. Labeling
12. Product Evaluation
13. Packaging
14. Storage, Distribution, and Installation
15. Complaints
16. Servicing
17. Quality Systems Audits
18. Factory Inspections
19. Appendix (Index of appendices)
    a. Appendix 1: The Quality Systems regulation
    b. Appendix 2: Application of the Medical Device GMPs to Computerized Devices and Manufacturing Processes.

4. Design Input *[state]*

Design input is the starting point for product design. The requirements that form the design input establish a basis for performing subsequent design tasks and validating the design.

- Establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including **[…]**
- **[…]**
- The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

These requirements are not literal prescriptions, but rather a set of principles to be followed. Here are some examples:

Initially, the Design Input is a concept document specifying some of the desired characteristics of the new product. Such concept documents are rarely comprehensive, and should not be expected to be so. Rather, the intent of the quality system **[…]**

It may be reasonable to develop a rapid prototype to explore the feasibility of an idea or design approach, for example, prior to developing design input requirements. But don't equate the prototype design with **[…]**

Regardless of who developed the initial product concept, the product developer(s) ultimately bear responsibility for translating user and/or patient needs into a set of requirements that can be validated prior to implementation. While this is primarily an engineering function, the support or full participation of **[…]**

Design input requirements must be comprehensive. This may be quite difficult for manufacturers who are implementing a system of design controls for the first time **[…]**

- Functional: what it does, processing of inputs into outputs...
- **[…]**

What is the scope of the design input requirements, and how much detail must be provided? The scope is dependent upon the complexity of a device and the risk associated with **[…]**

Eventually, the design input must be reviewed for adequacy. After review and approval, the design input becomes **[…]**

Verification activities will often uncover discrepancies, which result in changes to the design input requirements. Keep in mind:

- The change control process for design input requirements must be carefully managed. Often, a design change to correct one problem may create a new **[…]**
- Extensive rework of the design input requirements suggests that the design input requirements may not be elaborated to a suitable level of detail, or insufficient resources are being devoted to defining and reviewing the requirements **[…]**

At the end of the major aspects of the design input stage, the design input requirements shall be documented and shall be **[…]**

- **[…]**

5. Design Output *[state]*

The requirements for Design Output can be separated into two elements:

- Design output should be defined and documented [expressed] in terms that allow adequate assessment of conformance to **[…]**
- **[…]**

This raises two fundamental issues for developers:

- What constitutes design output?
- Are the form and content of the design output suitable?

5.1. What constitutes Design Output

As a general rule, an item is design output if it is a work product, or deliverable item, of a design task listed in the design and development plan, and the item **[…]**

Design output includes “Production Specifications” as well as “Descriptive Materials” which define and characterize the design.

Production Specifications: Production specifications include drawings and documents used to procure components, fabricate, **[…]** such as the following:

- Assembly drawings
- **[…]**

Descriptive Materials: Other design output items might be produced which are necessary to establish conformance to design input requirements, but are not used in its production. For example, **[…]** Other examples of design output include the following:

- The results of risk analysis
- **[…]**

Documenting design output in terms that allow an adequate evaluation of conformance to design input requirements is a significant requirement and design activity. A common technique for achieving this conformance is listed here:

- Convert the general input requirements to **[…]**
- Develop the design to meet all of the parameters and characteristics **[…]**
- **[…]**

Each of these documents has a different drawing number but the line/paragraph numbers are the same. The first of these documents may be used as the beginning format for the next one. Therefore, **[…]**

5.2. What Form and Content should it take?

We must assure that the design output characterizes all important aspects of the design and is expressed in terms that allow adequate verification and validation. Two basic mechanisms are available **[…]**

1. The manufacturer proactively can specify the form and content of design output at the planning stage. For some types of design output **[…]**
2. Form and content can be reviewed retroactively as a part of the design verification process. For example **[…]**

These requirements concerning design output generally requires no “extra” effort on the part of the manufacturer, but **[…]**

6. Specification, Verification, and Validation *[transitions]*

These terms can be confusing, and often overlap.

SPECIFICATION means any requirement with which a product **[…]**

VALIDATION means confirmation by examination and **[…]**

1. Process Validation means establishing by objective evidence that **[…]**
2. Design Validation means establishing by objective evidence that **[…]**

VERIFICATION means confirmation by examination and **[…]**

MZ: I believe, for software development, a key difference between Verification and Validation is: **[…]** From FDA:

- Design validation means **[…]**
- Verification means **[…]**

Verification and validation are associated concepts with very important differences. Be sure to use the terminology of the quality system requirements in internal procedures.

Consider a building design analogy. **[…]**

Verification is the process of checking at each stage whether the output conforms to requirements for **[…]**

Validation: At the same time, the architect has to keep in mind the broader question of whether the results are consistent with **[…]**

In the initial stages of design, verification is a key quality assurance technique. As the design effort progresses, verification activities become **[…]**

Validation follows successful verification, and ensures that each requirement for a particular use is **[…]**

7. Verification Output *[state]*

- Each manufacturer shall establish and maintain procedures for verifying the device design.
- 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 Design History File.

The basis of verification is a three-pronged approach involving **[…]**

Many of these practices are an integral part of the development process, and are routinely performed by **[…]**

Following are a few examples of verification methods and activities.

- Fault tree analysis of a process or design.
- Failure modes and effects analysis.
- **[…]**

Verification is NOT production testing, which **[…]**

DOCUMENTATION OF VERIFICATION ACTIVITIES. Some verification methods result in a document by their nature. For example **[…]**

Another self-documenting verification method is the traceability matrix. This method is particularly useful when **[…]**

However, many verification activities are simply some sort of structured assessment of the design output relative to the design input. When this is the case, **[…]**

8. Validation Output *[state]*

Whereas verification is a detailed examination of aspects of a design at various stages in the development, design validation is a cumulative summation of **[…]**

- Each manufacturer shall establish and maintain procedures for validating **[…]**
- Design validation shall be performed under defined operating conditions **[…]**
- **[…]**

VALIDATION PLANNING. Planning for validation should begin early in the design process. The performance characteristics that are to be assessed should be **[…]**

VALIDATION REVIEW. Validation may expose deficiencies in the original assumptions ... A formal review process should be used to resolve **[…]**

VALIDATION METHODS. Many medical devices do not require clinical trials. However, all devices require clinical evaluation and **[…]**

VALIDATION DOCUMENTATION. Validation is a compilation of the results of all validation activities. For a complex design, **[…]**

From **[…]**

8.1. Software Validation

Software is evaluated and reviewed versus the software specifications during the ongoing development of the device design. When a “final” prototype(s) is available, the software and hardware are **[…]**

Before testing the software in actual use, the detailed code should be **[…]**

In all cases, algorithms should be checked for accuracy. Recalls **[…]**

The validation program is planned and executed such that all relevant elements of the software and hardware are **[…]**

The testing includes normal operation of the complete device; and this phase of the validation program may be completed first **[…]** As appropriate, these inputs and conditions include such items as:

- Induced failure of sensors and cables or other interconnects;
- **[…]**

The results of the software and combined device system validation are included in the design reviews.

9. Design Review *[transition]*

- The procedures shall ensure that participants at each design review include **[…]**
- **[…]**

Design review means a documented, comprehensive, systematic examination of a design to evaluate the **[…]**

In general, formal design reviews are intended to:

- Provide a systematic assessment of **[…]**
- **[…]**

Design Reviews can occur throughout the development process, for example:

Design Input, Review, Design Output, Review, Verification, Review, Validation, Review, etc. The nature of reviews changes as the design progresses. During the initial stages, issues related to design input requirements will **[…]**

The number of formal design reviews depends on the scope and complexity of **[…]**

The term “review” is commonly used by manufacturers to describe a variety of design assessment activities. Most, but not all, of these activities **[…]**

- Evaluation activities like peer review, supervisory review, tech assessment, **[…]**
- **[…]**

9.1. Number and Type of Reviews

- For complex software development, it commonly includes a high-level design phase, during which **[…]**

- **[…]**

What is important is that the manufacturer establishes a reasonable rationale for the number and type of reviews **[…]**

Neither the Verification Review nor the Validation Review is explicitly shown in the FDA waterfall picture, but **[…]**

The FDA documents make it extremely clear that a Review is necessary after Design Verification. They are less emphatic about **[…]**

- The results of the software and combined device system validation are included in the design reviews.
- **[…]**

9.2. Selection of Reviewers

Expertise: Formal design reviews should be conducted by person(s) having technical competence and experience at least comparable to **[…]**

Independence. The formal design review should include at least one individual who does not have direct responsibility for **[…]**

9.3. Design Review Procedures

The manufacturer should have documented formal design review procedures addressing the following:

- Evaluation of the design (including identification of concerns, i.e., **[…]**
- **[…]**

Evaluation of the design: Many formal reviews are via meeting (e.g., designers present design implementation, and verification people **[…]**

Resolution of concerns: Lots of latitude here; **[…]**

Implementation of corrective actions: Can result in design and/or requirements **[…]**.

10. TAGSYS (CVS TAG System)

The following procedure is used to tie the current versions of software and documentation to a particular SCR step and phase. It assumes the existence of **[…]**

- Information on SCR step and phase is recorded in HISTORY.
- **[…]**

At any later time, those versions of software and documentation can be recovered via ‘cvs update -r TAG_NAME’

END OF: Quality System: Design Control Procedure - Appendix

