

Guide to Inspections of Quality Systems

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Quality System
Inspection Technique

QSIT



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Important linkages

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This reference is intended to be used in conjunction with the:

- Compliance Program Guidance Manual for Inspection of Medical Device Manufacturers (CP 7382.845).
- Investigations Operations Manual (IOM).
- Code of Federal Regulations, Title 21 (21 CFR) Part 820 Quality System Regulation; Part 803 Medical Device Reporting; Part 806 Medical Device Corrections and Removals; Part 821 Medical Device Tracking.
- Compliance Policy Guides (CPG) for devices (Sub Chapter 300).
Guidance on General Principles of Process Validation, FDA, May 1987.
- references in
- The Federal Food, Drug, and Cosmetic Act; The Safe Medical Devices Act (SMDA) of 1990 and the Medical Device Amendments of 1992.
- Medical Device Quality Systems Manual: A Small Entity Compliance Guide.
- The FDA Worldwide Quality System Requirements Guidebook for Medical Devices.
- Other device specific guidance documents prepared by CDRH for the medical device industry.
- FDA Recognized Standards.

These additional guidances are posted to the CDRH Internet World Wide Web Home Page at <http://www.fda.gov/cdrh>.
See IOM Chapter 10, References, for additional information.

Management Controls

Narrative

<p>Purpose/Importance</p> <p>The purpose of the management control subsystem is to provide adequate resources for device design, manufacturing, quality assurance, distribution, installation, and servicing activities; assure the quality system is functioning properly; monitor the quality system; and make necessary adjustments. A quality system that has been implemented effectively and is monitored to identify and address problems is more likely to produce devices that function as intended.</p> <p>A primary purpose of the inspection is to determine whether management with executive responsibility ensure that an adequate and effective quality system has been established (defined, documented and implemented) at the firm. Because of this, each inspection should begin and end with an evaluation of the subsystem.</p>
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- 1. Verify that a quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined and documented.**

Prior to the start of the inspection, preferably at the time you make the preannouncement of the inspection (if preannounced), you should ask the firm to send you their overall (or top level) quality system policies, objectives, and procedures. This should include their management review procedures, quality policy, and quality plan. If not received prior to the start of the inspection, you will need to review these documents at the start of your inspection.

Quality Policy and Objectives

The firm must have a written quality policy. The definition of quality policy is provided in the Quality System Regulation. It means the overall intentions and directions of an organization with respect to quality. The firm is responsible for establishing a clear quality policy with achievable objectives then translating the objectives into actual methods and procedures. Management with executive responsibility (i.e. has the authority to establish and make changes to the company quality policy) must assure the policy and objectives are understood and implemented at all levels of their organization. The policy does not need to be extensive. Personnel are not required to be able to recite the policy but they should be familiar with it and know where to obtain it.

Management Review and Quality Audit Procedures

Management reviews and quality audits are a foundation of a good quality system. Assure that the manufacturer has written procedures for conducting management reviews and quality audits and there are defined intervals for when they should occur. The firm's quality audits should examine the quality system activities to demonstrate that the procedures are appropriate to achieve quality system objectives, and that procedures have been implemented. A successful implementation of the firm's procedures should result in the firm achieving its quality policy and associated objectives. Whether the quality policy and objectives are "good" may become evident as the other subsystems are reviewed during the inspection.

Quality Plans

Firms must have a written quality plan that defines the quality practices, resources and activities relevant to the device that are being manufactured at the facility. The manufacturer must have written procedures that describe how they intend to meet their quality requirements.

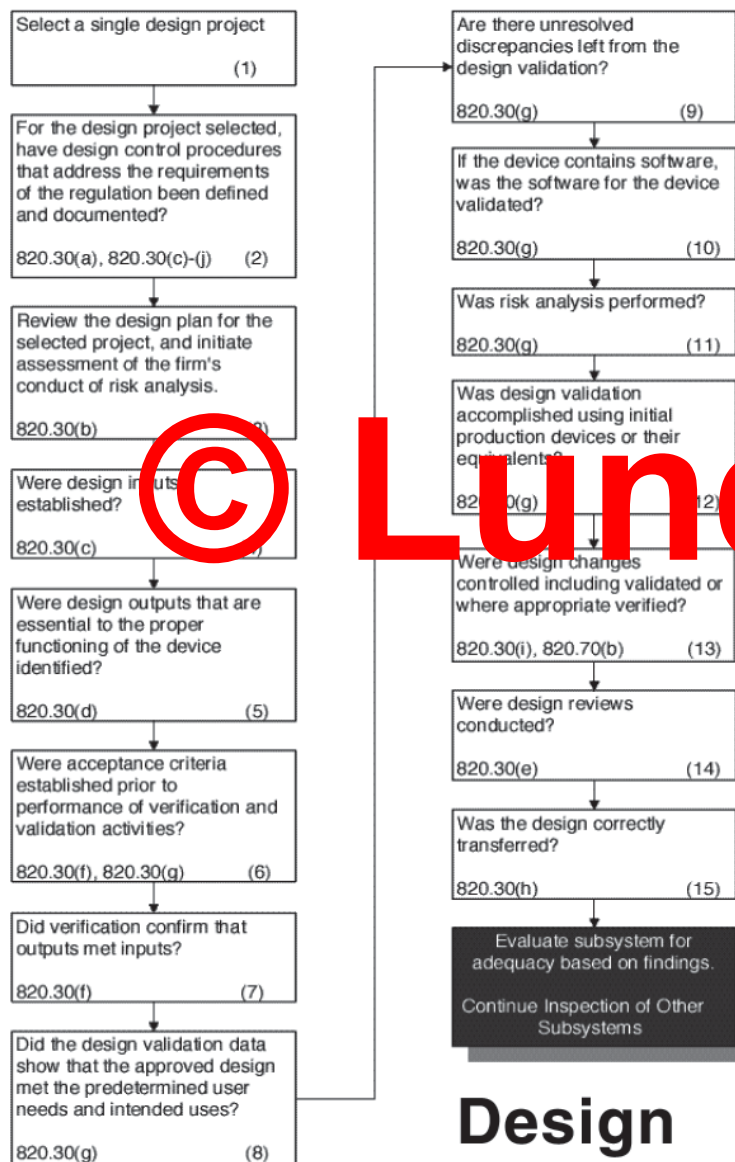
For firms that manufacture devices as well as other products, there must be a quality plan that is specifically relevant to devices. Much of what is required to be part of the plan may be found in the firm's quality system documentation, such as, the Quality Manual, Device Master Record(s), production procedures, etc. Therefore, the plan itself may be a roadmap of the firm's quality system. The plan in this case would need to include reference to applicable quality system documents and how those documents apply to the device(s) that is the subject of the plan.

Quality plans may be specific to one device or be generic to all devices manufactured at the firm. Quality plans can also be specific to processes or overall systems.

Quality System Procedures and Instructions

All manufacturers of medical devices are required to establish and implement a quality system tailored to the device manufactured. Each manufacturer must prepare and implement all activities, including, but not necessarily limited to the applicable requirements of the Quality System Regulation, that are necessary to assure the finished device, the design process, the manufacturing process, and all related activities conform to approved specifications.

The term "quality system" as specified in the Quality System Regulation encompasses all activities previously referred to as "quality assurance" which were necessary to assure the finished device meets its predetermined design specifications. This includes assuring manufacturing processes are controlled and adequate for their intended use, documentation is controlled and maintained, equipment is calibrated, inspected, tested, etc. Some manufacturers may use the terms "quality control" or "GMP Control" or "quality assurance" instead of quality system.



Design Controls Decision Flow Chart

Design Controls

Narrative

Purpose/Importance

The purpose of the design control subsystem is to control the design process to ensure that devices meet user needs, intended uses, and specified requirements. Attention to design and development planning, identifying design inputs, developing design outputs, verifying that design outputs meet design inputs, validating the design, controlling design changes, reviewing design results, transferring the design to production, and compiling a design history file help ensure that resulting designs will meet user needs, intended uses and requirements.

Select a single design project

Note: If the project selected involves a device that contains software, consider reviewing the software's validation while proceeding through the assessment of the firm's design control system.

The design control requirements of Section 820.30 of the regulation apply to the design of Class II and III medical devices, and a select group of Class I devices. The regulation is very flexible in the area of design controls. The type of design control system and the precise details of implementation are left for each firm to decide based on the complexity and risks associated with their devices.

If design control requirements are applicable to the operations of the firm, *select a design project*. Unless the inspection assignment directs the inspection of a particular design project, select a project that provides the best challenge to the firm's design control system. This project will be used to evaluate the process, the methods, and the procedures that the firm has established to implement the requirements for design controls.

Do not inspect a device under design control requirements to determine whether the design was appropriate or safe and effective. This is precluded under Section 520(f)(1)(A) of the Act. However, if based on information obtained during an evaluation of the firm's design controls, it appears that the device is unsafe or ineffective, then report those findings in the EIR.

The requirement for software validation is included in Section 820.30(g) Design Validation. However, if the project selected involves a device that contains software, consider reviewing the software's validation while proceeding through the assessment of the firm's design control system.

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