Quality System (QS) Regulation/Medical Device Good Manufacturing Practices

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Introduction

Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biologics, and devices) are known as current good manufacturing practices (CGMP's). CGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act). Under section 520(f) of the act, FDA issued a final rule in the Federal Register of July 21, 1978 (43 FR 31 508), prescribing CGMP requirements for medical devices. This regulation became effective on December 18, 1978, and was codified under part 820.

In 1990, FDA undertook the start of the revision of the CGMP regulation to add the design controls authorized by the Safe Medical Devices Act. Also, the agency believed that it would be beneficial to the public and the medical device industry for the CGMP regulation to be consistent, to the extent possible, with the requirements for quality systems contained in applicable international standards, primarily, the International Organization for Standards (ISO) 9001:1994 "Quality Systems--Model for Quality Assurance in Design, Development, Production, Installation, and Servicing," and at the time the ISO committee draft (CD) revision of ISO/CD 13485 "Quality Systems--Medical Devices--Supplementary Requirements to ISO 9001." After an extensive effort, the part 820 revision was published on October 7, 1996 **(61 FR 52602) ()** and went into effect June 1, 1997. For additional information on the history and international harmonization of the revised regulation, with international standards and the Global Harmonization Task Force (GHTF), see the preamble (pages 52602 - 52654) to the Quality System regulation **(61 FR 52602) ()**.

The preamble describes the public comments received during the development of the QS regulation and describes the FDA Commissioner's resolution of the comments. Thus, the preamble contains valuable insight into the meaning and intent of the QS regulation.

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Flexibility of the QS Regulation

The QS regulation embraces the same "umbrella" approach to the CGMP regulation that was the underpinning of the original CGMP regulation. Because the regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.

Manufacturers should use good judgment when developing their quality system and apply those sections of the QS regulation that are applicable to their specific products and operations, 21 CFR 820.5 of the QS regulation. Operating within this flexibility, it is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements. The responsibility for meeting these requirements and for having objective evidence of meeting these requirements may not be delegated even though the actual work may be delegated.

FDA has identified in the QS regulation the essential elements that a quality system shall embody, without prescribing specific ways to establish these elements. Because the QS regulation covers a broad spectrum of devices, production processes, etc., it allows some leeway in the details of quality system elements. It is left to manufacturers to determine the necessity for, or extent of, some quality elements and to develop and implement specific procedures tailored to their particular processes and devices.

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Applicability of the QS Regulation

The QS regulation applies to finished device manufacturers who intend to commercially distribute medical devices. A finished device is defined in 21 CFR 820.3(l) as any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Certain components such as blood tubing and diagnostic x-ray components are considered by FDA to be finished devices because they are accessories to finished devices. A manufacturer of accessories is subject to the QS regulation.

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GMP Exemptions

FDA has determined that certain types of medical devices are exempt from GMP requirements. These devices are exempted by FDA classification regulations published in the Federal Register and codified in 21 CFR 862 to 892. Exemption from the GMP requirements does not exempt manufacturers of finished devices from keeping complaint files (21 CFR 820.198) or from general requirements concerning records (21 CFR 820.180).

Medical devices manufactured under an investigational device exemption (IDE) are not exempt from design control requirements under 21 CFR 820.30 of the QS regulation.

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Additional Quality System Information

Quality System (QS) Regulation

- **21 CFR 820 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1)**
- **Medical Device Quality System Regulation and Preamble (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm)**

Quality System Regulation Guidance Documents

- **Quality System Information for Certain Premarket Application Reviews - Guidance for Industry and FDA Staff (PDF - 548KB) (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070899.pdf)**

Design Controls

- **Design Control Guidance For Medical Device Manufacturers (PDF - 179KB) (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070642.pdf)**

Human Factors

- **Human Factors and Medical Devices (/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/default.htm)**

Other Related Information

- **Workshops & Conferences (Medical Devices) (/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm)**
- **CDRH Learn (/Training/CDRHLearn/default.htm)**
- **What is the relationship between FDA's Quality System Regulation for Devices, Part 820 and ISO 9001: 2000? (PDF - 10KB) (/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/UCM134625.pdf)**

More in Quality Systems Regulation (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm)