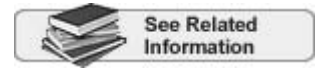




Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation



The Good Manufacturing Practices (GMP) regulation, is contained in section 520 of the Food, Drug and Cosmetic Act. It requires that domestic or foreign manufacturers of medical devices intended for commercial distribution in the United States establish and follow a quality assurance (QA) program. The GMP rule is a flexible program in that it allows a quality assurance program which is appropriate for the specific devices. The regulation requires that specifications and controls be established for devices and that finished devices meet these specifications. In this way, the GMP regulation helps assure that medical devices are safe and effective.

Analysis of recalls and adverse reaction reports show that about half of reported device failures involve traditional GMP problems. Between 1985 and 1989, FDA compiled data through its recall database that demonstrated that 45 to 50 percent of all device recalls stemmed from poor product design (including problems with software). Congress, alarmed by this, asked FDA to identify enforcement mechanisms to address the issue. FDA responded that design controls or enhanced GMP controls were needed. As a result, Congress passed the Safe Medical Devices Act (SMDA) of 1990, which gives FDA authority to require good manufacturing practices necessary to ensure proper device design.

To act on this mandate, the FDA revised the GMP requirements for medical devices and incorporated them into a quality system regulation. The Quality System Regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices intended for human use. The revised GMP Regulation was released as a final rule on October 7, 1996. The section that deals specifically with design controls is section 820.30 of Title 21, of the Code of Federal Regulations ("21 CFR"). 21 CFR 820.30 requires manufacturers to establish and maintain procedures to control and verify device design to ensure that design requirements are met. More specifically, it requires manufacturers to establish and maintain plans that describe or reference the design and development activities and indicate responsibility for their implementation. It further requires manufacturers to establish and maintain procedures to ensure that design requirements relating to a particular device are appropriate and address the intended use of the device, including the needs of users and patients. It also requires manufacturers to establish and maintain procedures to ensure that design output meets the design input requirements. The regulation is effective June 1, 1997.

Selected Portions of the New Quality System Regulation that Apply to Human Factors

Shown below are subparts A-D of the new Quality System Regulation which address the newly added design controls. Specifically, see Subpart C -- Design Controls, § 820.30 Design controls. The need for human factors techniques or data in the design process is implicit in paragraphs c, f, and g of Section 820.30 discussed below. It should be noted, however, that human factors techniques and data should be an integral consideration in all the other design control components as well.

(c) Design input:

"Each manufacturer shall 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 needs of the users and patient."

- Human factors relevance: Ensuring proper design of the user interface of a device is critical to address the user's needs. This is best done by systematic consideration of human factors in the development of the

device user interface. The user interface includes all aspects of a device (including its labeling) that users see, feel and hear when operating the device.

(f) Design verification:

"Each manufacturer shall establish and maintain procedures for verifying the design input. Design verification shall confirm that the design output meets the design input requirements."

- Human factors relevance: For both establishing the design input for the user interface, and carrying out design verification, manufacturers should conduct human factors activities throughout the design program. These activities can include task/function analyses, user studies, prototype tests and mock-up reviews.

(g) Design validation:

"Design validation shall ensure that devices conform to defined user needs and intended uses, and shall include testing of production units under actual or simulated use conditions."

- Human factors relevance: Design validation should be used to demonstrate that the potential for use error that can lead to patient injury has been minimized. The regulation requires testing the device under actual or simulated use conditions. Realistic use conditions, therefore, should be carried out by test participants who represent a range of typical intended users in terms of their ability to acquire information from, manipulate and maintain the device and understand the accompanying labeling.

"Design validation shall include...risk analysis..."

Human factors relevance: In addition to other hazards, risk analysis should include use error as well. A risk analysis is appropriate for any device where use error can lead to serious patient injury.

Medical Devices; Current Good Manufacturing Practices (CGMP) Final Rule; 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

- [§ 820.30 Design Controls](#)

Subpart D - Document Control

- [§ 820.40 Document Controls](#)

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