

Glisland® Training Series:

Quality System Regulation

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GMP & cGMP vs. QSR

1. GMP – Good Manufacturing Practice
2. cGMP – Current Good Manufacturing Practice
3. QSR – Quality System Regulation

“Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation.”

“The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.”



Device Related Laws

1. Federal Food, Drug & Cosmetic Act of 1938
2. Medical Device Amendments Act of 1976
3. Safe Medical Devices Act of 1990
4. Medical Device Amendments of 1992
5. FDA Export Reform and Enhancement Act of 1996
6. FDA Modernization Act of 1997
7. Medical Device User Fee and Modernization Act of 2002
8. FDA Amendments Act of 2007

FDA Quality System Regulation

1. In 1976, cGMP for medical devices: 520(f) of FD&C Act (21 U.S.C. 360j(f))
2. Codified in 21 CFR Part 820, effective December 1978
3. Focused on production process in 1978 cGMP
4. Added design control provision in 1990 amended by *SMDA (Safe Medical Device Acts)*
 - a) Added section 803 (21 U.S.C 383)
 - b) Revised 1978 cGMP and harmonized with EU standard
 - c) Rename cGMP for medical device to QSR
 - d) Design Control effective June 1, 1998
5. The new QSR applies to the entire life cycle of a device



21 CFR Part 820 Components

1. General Provisions
2. Quality System Requirements
3. Design Controls
4. Document Controls
5. Purchasing Controls
6. Identification and Traceability
7. Production and Process Controls
8. Acceptance Activities
9. Nonconforming Product
10. Corrective and Preventive Action
11. Labeling and Packaging Control
12. Handling, Storage, Distribution, and Installation
13. Records
14. Servicing
15. Statistical Techniques



Subpart A - General Provisions

1. Scope (§ 820.1)

- a) From design, manufacture, packaging, labeling, storage, installation, to servicing
- b) Finished devices intended for human use
- c) Some Class I devices
- d) Device HTC/Ps
- e) Made in US or imported
- f) “where appropriate”

2. Definitions (§ 820.3)

3. Quality system (§ 820.5)

- a) *Quality system* (QS) means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management
- b) Establish and maintain QS

Subpart B -

Quality System Requirements

- 1. Management responsibility (§ 820.20)**
 - a) Quality policy and objectives
 - b) Adequate organizational structure
 - c) Management review at defined sufficient intervals
 - d) Quality planning
 - e) Quality system procedures
- 2. Quality audit (§ 820.22)**
 - a) Procedures, CAPA, review, documentation
- 3. Personnel (§ 820.25)**
 - a) Sufficient and qualified
 - b) Training



Subpart C - Design Controls

- a) Any class III, class II, and some class I (820.(a)(2))
- b) Design and development planning: establish, review, update, approve
- c) Design input: SOPs, requirements, review and approval
- d) Design output: SOPs, acceptance criteria, review and approval
- e) Design review: SOPs, representatives
- f) Design verification: design output <-> design input
- g) Design validation: production units <-> intended use
- h) Design transfer: SOPs
- i) Design changes: review and approval before change
- j) Design history file: for each type of device



Subpart D - Document Controls

Establish and maintain procedures to control **all documents** that are required by this part:

- a) Document approval and distribution
 - Review and approval prior to issuance
 - Available at all locations necessary
 - Remove obsolete documents promptly
- b) Document changes
 - Original review and approval
 - Timely communication of changes
 - Change records



Subpart E - Purchasing Controls

Establish and maintain procedures to ensure that **all purchased** or otherwise received product and services **conform to specified requirements:**

- a) Evaluation of suppliers, contractors, and consultants
 - Set requirements
 - Evaluate ability to meet the requirements
 - Controls
 - Records
- b) Purchase data
 - Specification
 - Agreements
 - Approval according to 820.40

Subpart F –

Identification and Traceability

1. Identification (§ 820.60)

Identify product during all stages of receipt, production, distribution, and installation to prevent mixups.

2. Traceability (§ 820.65)

- Surgical implants
- Life support or sustain devices
- Control number
- Corrective action procedures
- DHR (Device History Record)

Subpart G –

Production and Process Controls

- 1. Production and process controls (§ 820.70)**
 - a) Develop, conduct, control, and monitor production processes
 - b) Production and process change control (validate/verify/approve)
 - c) Environmental control (e.g. air conditioning)
 - d) Personnel: health, cleanliness, personal practice, clothing, training
 - e) Contamination control
 - f) Buildings: sufficient space, prevent mixups
 - g) Equipment: Validation, maintenance
 - h) Control of manufacturing materials
 - i) Automated processes: software validation



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