QUICK GUIDE: GLOSSARY OF KEY QUALITY SYSTEM REGULATIONS

Abstract

The glossary consolidates key FDA quality system regulations and guidance for medical devices, pharmaceuticals, and biologics. It offers quick access to critical regulatory standards, helping professionals ensure compliance and maintain product quality.

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Glossary of Key Quality System Regulations

In the dynamic fields of medical devices, pharmaceuticals, and biologics, maintaining compliance with FDA quality systems regulations is critical for ensuring product safety, efficacy, and marketability. This glossary serves as a quick reference guide for researchers, quality professionals, and regulatory experts seeking to understand and apply key FDA rulings. It provides succinct summaries of relevant regulations and guidance documents, which are essential in shaping the quality frameworks that underlie product development and manufacturing processes.

From current Good Manufacturing Practices (cGMP) to post-market surveillance and cybersecurity requirements, these documents offer the latest regulatory insights and best practices. Each entry includes a direct link to the original FDA source, ensuring that professionals can access the most accurate and up-to-date information for their compliance needs.

1. **21 CFR Part 820** – Quality System Regulation (QSR): Sets current good manufacturing practices (cGMP) for medical device manufacturers to ensure consistent product quality.
   Link:
   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820
2. **21 CFR Part 211** – Current Good Manufacturing Practices (cGMP) for Finished Pharmaceuticals: Establishes minimum standards for the methods, facilities, and controls used in manufacturing, processing, packing, or holding of pharmaceuticals.
   Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211
3. **21 CFR Part 11** – Electronic Records and Electronic Signatures: Specifies criteria under which electronic records and signatures are considered equivalent to paper records and handwritten signatures.
   Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11
4. **21 CFR Part 58** – Good Laboratory Practice for Nonclinical Laboratory Studies: Governs the conduct of nonclinical laboratory studies that support research or marketing permits for products regulated by the FDA.
   Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-58
5. **21 CFR Part 803** – Medical Device Reporting (MDR): Requires manufacturers, importers, and device user facilities to report adverse events and product problems to the FDA.
   Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803
6. **21 CFR Part 820.30** – Design Controls: Defines procedures for design and development to ensure device specifications conform to intended use.
   Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/subpart-C/section-820.30
7. **21 CFR Part 4** – Combination Product cGMP Requirements: Defines the quality system framework for products that combine drugs, devices, and/or biological products.
   Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-4

8. **21 CFR Part 50** – Protection of Human Subjects: Sets standards for clinical trials, ensuring ethical treatment and informed consent of participants.
   Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50
9. **21 CFR Part 54** – Financial Disclosure by Clinical Investigators: Requires financial disclosure from investigators to prevent conflicts of interest in FDA-regulated clinical trials.
   Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-54
10. **21 CFR Part 600** – Biological Products: General Requirements: Governs the manufacturing, testing, and reporting requirements for biological products like vaccines and blood products.
    Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-600
11. **21 CFR Part 610** – General Biological Product Standards: Details additional quality and safety standards for biological products, including purity, sterility, and identity testing.
    Link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-610

FDA Guidance documents for Industry

12. **Process Validation**: Outlines recommended practices for establishing, controlling, and validating manufacturing processes to ensure product quality.
    Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-validation-general-principles-and-practices
13. **Risk-Based Approach to Monitoring Clinical Trials:** Encourages the adoption of risk-based methodologies to focus oversight on critical data and processes in clinical trials.
    Link: https://www.fda.gov/media/121479/download
14. **Post market Surveillance Under Section 522:** Mandates post market surveillance for certain high-risk devices to gather long-term safety and effectiveness data.
    Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act
15. **Medical Device Quality System Inspections Technique (QSIT):** Provides an inspectional tool to assess the adequacy of a medical device manufacturer's quality system.
    Link: https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/medical-device-premarket-approval-and-postmarket-inspections-part-iii-inspectional
16. **Premarket Submissions for Device Software Functions:** Offers recommendations on software documentation to include in premarket submissions for medical devices.
    Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions
17. **Human Factors and Usability Engineering for Medical Devices:** Describes best practices for integrating human factors into the design of medical devices to reduce use-related errors.

Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices

18. **Unique Device Identifier (UDI) Rule:** Requires the labeling of medical devices with a unique identifier to improve traceability and recall efficiency.
    Link: https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system

19. **Content of Premarket Submissions for Management of Cybersecurity in Medical Devices:** Specifies the necessary cybersecurity controls that should be incorporated into medical device submissions.
    Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions

20. **Quality Considerations for Clinical Research:** Sets standards to maintain high-quality and integrity in clinical research, particularly focusing on trial design and data management practices.
    Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e8r1-general-considerations-clinical-studies

This glossary covers essential FDA regulations and guidance documents related to quality systems in the medical device, pharmaceutical, and biological products industries.

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Enabling you Transition RUO Products to FDA Approved

At QuRA Solutions, we specialize in providing comprehensive solutions for companies looking to transition their research-use-only (RUO) products to FDA-approved products. Our team of experts brings together decades of experience in regulatory affairs, quality management, and strategic marketing, ensuring a seamless journey from concept to market. Discover how our expertise can drive your product's success.

Our Team

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Our Services

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Partner with us to transform your innovative ideas into market-ready products. Contact us today to learn more about how we can support your journey from research to regulatory approval

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