

Medical Device Validation and Verification Testing

The FDA Quality System Regulation (QSR, 21 CFR Part 820) includes a requirement for manufacturers to implement a quality system for the design, manufacturing, packaging, labeling, storage and delivery of medical devices. MKCS Compliance and Qualification Services helps our customers to:

- Develop and implement systems and procedures to effectively document the medical device design history process
- Implement risk management and design validation processes and procedures
- Identify the most appropriate and relevant testing standards and requirements for your technology
- Implement customized solutions to your business needs.

Relevant Guidance Documents:

Medical Device Quality System Manual: A Small Entity Compliance Guide
(<http://www.fda.gov/cdrh/dsma/gmpman.html>)

Guidance for Industry: General Principles of Software Validation
(<http://www.fda.gov/cdrh/comp/guidance/938.pdf>)

Medical Devices; Current Good Manufacturing Practice Final Rule; Quality System Regulation (GMP) (<http://www.fda.gov/cdrh/fr1007ap.pdf>)

Medical Device GMP Guidance for FDA Investigators
(<http://www.fda.gov/cdrh/qsr/appdx2.pdf>)