



Compliance Solutions for Medical Devices

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BioQuality ™ is a provider of innovative, cost-effective quality, compliance, and regulatory solutions for Medical Device and Healthcare industries. Over 20 years, the BioQuality ™ team with leadership & authority has provided innovative/cost-effective compliance solutions based on risk management, technology and current FDA thinking.

BioQuality ™ Core Services include the following:

- ✓ **Quality Systems** (FDA QSR/ISO QMS)
- ✓ **Verification & Validation** (V&V, QA)
- ✓ **Audits & Certifications** (Internal/Vendors)
- ✓ **Compliance Training** (cGMP /QSR)
- ✓ **Business Process Improvements** (6σ)
- ✓ **Regulatory Compliance** (FDA/EU/ISO)

Supporting Services

- *Product Development & Assurance*
- *Design Control (QSR)& Validation*
- *Product & Process Validation*
- *System Integration (SW/HW/FW)*
- *Verification & Validation (V&V)*
- *Quality System Regulations (QSR)*
- *Risk Management (FMEA/FTA/HA)*
- *Independent Reviews, Testing & QA*
- *Design History File (DHF) & DMR etc.*
- *Quality & Compliance Training*
- *Audits & Inspections (internal/suppliers)*
- *IDE documentation and clinical support*
- *FDA 510(k) and PMA submissions*
- *FDA 483 – Remediation and support*
- *FDA/MDD Class III, II and I devices*
- *FDA warnings (483s) & Remediation*

Previous Projects or Products

- ⇨ *Implantable Cardiac Devices (ICDs)*
- ⇨ *IV Drug Delivery Infusion Pumps*
- ⇨ *Neuro and Spinal systems and pacemakers*
- ⇨ *Non-invasive Ultrasound handheld devices*
- ⇨ *ECG monitors, analyzers & related products*
- ⇨ *Tele-Medicine - Devices & Healthcare Solutions*
- ⇨ *Medical Devices - Connectivity & Integration*
- ⇨ *Embedded System (SW/HW) - Dev and Testing*
- ⇨ *Product Assurance – V&V, Testing & QA*

Regulations & Standards

- ♦ *FDA Medical Device - 21 CFR Part 820 (QSR)*
- ♦ *ISO 13485 & 14971 (medical device standards)*
- ♦ *FDA Pharmaceutical - 21 CFR Part 210/211 & 11*
- ♦ *MDR, EU Medical Device Directive, and CE Mark*
- ♦ *Security Compliance - COBIT, ITIL, ISO 17799*
- ♦ *Healthcare Regulations – HHS HIPAA/ HITECH*

Industry Leaders in Medical Device – Product Development, QA, Testing, V&V, FDA compliance, Audits, IDE/510(k)/PMA submissions, Documentation & Manufacturing.