



Compliance Solutions for HIT Systems

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BioQuality™ Services for HIT System Manufacturers/Suppliers/Vendors/Users:

- Cost-effective HIT Solutions & Implementations that comply regulations & standards
- Medical Devices - Interfaces, Connectivity, and Integration with existing systems
- Certifications by the CCHIT (*Certification Commission for Healthcare Information Technology*)
- Improve the KLAS – Overall Performance Ratings for Healthcare Software & Systems
- Establish Healthcare Regulations & Standards (FDA & HHS) programs/processes to comply
- Successful Certification process by optimum Testing while satisfying ISO 65 & 17025 standards
- Increase the Efficiency and Effectiveness by the Business Processes Improvements (*Six-Sigma*)
- Customize Risk Management plan to address Data breaches, Agreement violations, and Regulatory Compliance Training & Security & Privacy

BioQuality™ Core Services:

- ✓ **Regulatory Compliance**
 - FDA: 21 CFRs 820/11; HHS: HIPAA/ HITECH
- ✓ **Quality Systems**
 - QMS (FDA QSR) & ISO Guide 65 & ISO 17025
- ✓ **Verification & Validation**
 - Biomed Systems: SW/HW/FW Testing/QA (V&V)
- ✓ **Audits & Certifications**
 - Biomedical Systems Auditors for compliance
- ✓ **Compliance Training**
 - FDA/QSR, HIPAA, HITECH and ISO Training
- ✓ **Business Process Improvements**
 - Six Sigma, ITIL & Risk Management Processes



BioQuality™ Helps HIT Users & Vendors to get Certified as per HHS Standards:

HHS - 2011 CERTIFICATION CRITERIA

