



At qointa, we specialize in revolutionizing the Life Sciences industry with a comprehensive suite of specialized services. With an unwavering commitment to excellence and a proven track record of success, we are your go-to partner for quality management, regulatory compliance, software development, contract research, patient engagement, and digital transformation. With our expert team and cutting-edge technology, we help you navigate the complex world of MedTech, turning your vision into reality.

Medical Device Software Development

Planning & Strategy, including idea validation, feasibility studies and regulatory pathway analysis

Requirements & Design:

- Functional & technical specifications
- Risk assessment (ISO 14971)
- UI/UX prototyping – visualize and refine product before development

Development:

- Agile software development with secure coding practices
- Integration with hardware systems

Verification & Validation:

- End-to-end testing & defect resolution
- Compliance documentation (FDA 21 CFR Part 11, IEC 62304)

Launch & post-launch Support:

- Regulatory submission support
- Real-World Evidence (RWE) generation
- Maintenance, updates, and enhancements
- Ongoing compliance with evolving regulations

Quality and Regulatory Support

Pre-Market Submissions – FDA 510(k), CE Marking, CCC, MHLW etc.

Quality & Regulatory Remediation Services:

- Implementation of Quality Management System (FDA QSR, EU MDR/IVDR, ISO 13485)
- Data Privacy and Protection (US/EU)
- Gap Analysis with regard to regulatory compliance
- Corrective Action/Preventive Action (CAPA)
- Supplier Engineering

Data Integrity (DI) Remediation Services

Audits and Assessment Services

Design QA and Compliance (DQAC) Services:

- Compliance to IEC 60601-1 3rd Edition (Medical Equipment Safety)
- Compliance to IEC 62304 (Medical Device Software Lifecycle)
- Design Verification and Validation Services
- Product Risk management (Compliance to ISO 14971)

Computer Systems Validation & Compliance (CSVC) Services

Compliance to FDA 21 CFR Part 11 and EU Annex 11:

- Gap analysis and System Assessments
- Remediation (corrective action) planning

Digital and IT Systems/Software Validation based on FDA regulations:

- Process Automation, Lab Automation, Clinical, Enterprise Apps

Fast-track deliverables, including:

- Validation Planning; Risk and Compliance Assessments
- Validation Protocol Development
- Development and Execution of Test Scenarios and Cases
- Requirements Traceability & Final Report Documentation
- Configuration and Change Control Procedures
- Periodic Compliance Review to Maintain Validated State

IT Infrastructure Qualification & Data Center Compliance:

- Network, Server & Environmental Controls Validation
- Qualification of Backup, Recovery, and Disaster Recovery Systems

Other Value Added Services:

- CSV to CSA Transitioning Services
- Implementation of Agile and Digital Validation Framework

Strategy & Leadership Services

Thought Leadership & Advisory

Business & Project Strategy

Business Analysis & Solution Definition

Program Development & Implementation

Get in Touch:

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