



Inspection Readiness & Regulatory Documentation Support for Medical Device-Enabled Decentralized Clinical Trials (DCTs) in compliance with FDA, EU MDR 2017/745, ISO 13485, and global regulations

In clinical trials, audits and inspections are not a question of if—but when. For trials involving Point-of-Care (POC) or connected medical devices, the regulatory and inspection burden is even higher. Each device—whether investigational or commercial—must be traceable, validated, and fully documented in accordance with ISO 13485:2016, 21 CFR Part 820 (FDA), EU MDR 2017/745, and applicable country-specific regulations.

qointa AuditPrep is a specialized service that ensures your device data, processes, and documentation are inspection-ready—whether the audit comes from a health authority, an ethics board, a sponsor QA team, or a third-party inspector.

Why AuditPrep Is Essential

Across decentralized and hybrid studies, audit risks have expanded:

- New roles (importer, distributor) under EU MDR 2017/745
- Software and connected devices regulated as Software as a Medical Device (SaMD), including AI/ML-based solutions regulated under FDA's Software Precertification Program, EU MDR Annex XVI, and IMDRF SaMD guidelines
- Regional data privacy laws (GDPR, HIPAA, PIPL) impacting device workflows
- Increased focus on data integrity, version control, and cybersecurity

“If a health authority or sponsor auditor requested your full device documentation—including CE, DoC, UDI, and FSCA history—could you provide it within 48 hours?”

“How are you documenting regulatory response actions for device events like recalls, software updates, or urgent labeling changes?”

“Have you ever faced a regulatory inspection where the device training logs, version history, or validation files weren't complete or consistent across regions?”

“What's your process for conducting mock audits to ensure your sites and vendors are prepared for inspection?”

“Are your TMF artifacts for device compliance, risk files, and training records aligned with ISO 13485, GCP, and 21 CFR Part 11 standards?”

Risks we mitigate:

Risk

- Missing device documentation
- Incomplete FSCA or labeling logs
- No audit trail for training or version updates
- Unvalidated reuse of devices
- Undocumented change control

Regulatory Impact

- Regulatory finding; CAPA trigger
- Noncompliance with EU MDR/FDA
- TMF gaps; IRB rejection
- Ethics board or patient safety concerns
- Delays in trial approval or registration

AuditPrep = No Surprises, Full Readiness

Our Comprehensive Services

1. Audit-Ready Documentation Compilation

- Centralized binder creation for all device-related documentation:
- Align with GCP, ISO 13485, FDA 21 CFR Part 820, and 21 CFR Part 11

2. Mock Audits & Readiness Assessments

- Simulate inspections by:
- Identify gaps using tailored audit checklists (device classification, traceability, FSCA handling)
- Mock audits follow inspection frameworks such as FDA QSR (21 CFR 820), EU MDR Audit Checklist (Notified Body), and PMDA Clinical Trial Notifications (CTNs).

3. CAPA Documentation & Oversight

- Maintain study-specific Corrective and Preventive Action (CAPA) logs in compliance with ISO 13485:2016 Clause 8.5 and FDA 21 CFR 820.100.
- Track root cause analysis and closure actions for:
- Align with sponsor QMS and regulatory timelines

4. Regulatory Briefing Packs

- Create concise briefing summaries for study teams and inspectors:
- Tailor by jurisdiction to address localized compliance requirements

5. Triggered Event Documentation

- Prepare support files for: Field Safety Corrective Actions (FSCA), Urgent labeling changes, Software/firmware updates
- Coordinate required reporting per region (e.g., EUDAMED, FDA, NMPA)
- Ensure compliance with FSCA reporting per MDR Article 87, FDA 21 CFR Part 803, PMDA AE reporting, and NMPA post-marketing reporting requirements.

6. TMF & Inspection Submission Support

- Prepare and format documentation for pre-inspection delivery or virtual inspection portals
- Align TMF population with ICH E6(R2), EU Annex 11, FDA 21 CFR Part 312 and 812, and GCP inspection expectations from MHRA and Health Canada.

7. Portfolio-Level Audit Dashboards

- Visualize audit risk by:
- Track open findings, documentation status, and inspection milestones
- Include traceability matrix for device lifecycle: procurement → deployment → maintenance → decommissioning.

8. Regulatory Lessons Learned Integration

- Disseminate learnings across teams and studies
- Lessons learned should be incorporated into QMS updates per ISO 13485:2016 Clause 8.5.1, and documented in the Management Review outputs (Clause 5.6).

Why Choose qointa?

01

Regulatory Mastery

We excel in understanding and navigating complex regulatory requirements, ensuring compliance and product approval.

02

Quality Excellence

qointa is committed to helping you maintain the highest standards of quality throughout your operations.

03

Customized Solutions

We tailor our services to your specific needs, ensuring a personalized and effective approach.

04

Global Expertise

Our team has extensive experience in dealing with regulatory standards and compliance across the globe.

05

Holistic Approach

Our services cover every aspect of quality and regulatory support, offering a one-stop solution for your needs.

Partner with qointa to Ensure Ongoing Compliance

Whether your inspection is 6 months away or 6 days away, qointa AuditPrep makes sure your documentation is defensible, complete, and regulator-ready.

It's not just a binder—it's your proactive compliance defense, aligned with global regulatory standards.

Turn inspections into routine events. Be ready, be thorough, be compliant—with qointa AuditPrep.



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