Fractional Service Overview

Accelerate Your Medical Device Development with Fractional Quality and Operational Leadership

What We Do

Bringing a medical device to market requires robust quality systems and operational expertise, but early-stage companies often can't justify a full-time senior-leadership or the overhead of building compliant infrastructure from scratch.

As a small, focused consultancy, we work closely with a limited number of clients to provide personalized, hands-on support. Our fractional services solve your challenges by providing all the following at a fraction of the cost of a full-time hire:

- Experienced quality and operational leadership
- A turnkey ISO 13485-compliant QMS
- Part 11-compliant document control

With month-to-month flexibility, you can scale support up or down as your development roadmap and budget evolve, ensuring you have the right level of expertise at every stage without long-term commitments.

Start developing under a compliant system immediately, maintain audit-ready documentation, and gain strategic guidance from day one, saving months of setup time and allowing you to focus on what matters most: bringing your innovation to patients.

Why Choose Crane Medtech Partners

- Small team, deep engagement – no layers of junior staff
- Built specifically for venture-backed and early-stage teams
- Deep experience in Class III, implantable and neurotech
- Lean, phase-appropriate systems (no overbuilt eQMS)
- Execution-focused support, not theoretical consulting

Services

1. Quality Advisory Support

Provides comprehensive quality oversight and strategic consulting throughout the product development lifecycle. This integrated service ensures consistent quality management while offering flexible advisory support for complex regulatory and operational challenges.

Note: Access to partner network, (biocompatibility consultants, sourcing managers, etc.) included within the monthly fee for small projects/meetings on occasional basis if needed.

Core Services:

- Quality approval authority for all controlled documents and records according to established procedures
- Review of documents prior to release (technical design/manufacturing risk, completeness, compliance to procedures)
- Conducting and documenting incremental risk assessments for changes, including impact to product and/or QMS
- Reviewing supplier documentation (CoCs, test reports) for compliance
- Creating or customizing SOPs, work instructions, and templates
- Leading Risk Management deliverables including establish and implement Risk Management Plan, Hazard Analysis assessment and documentation, and updates based on changes to intended use, design, and new information
- Conducting and documenting design reviews
- Internal training on medical device development to build institutional knowledge, provided initially upon QMS implementation and ad-hoc throughout interactions as needed.

Advisory Services (as needed):

- Design control strategy and approach development
- Risk management strategy and methodology selection
- Supplier qualification strategy and criteria development
- Troubleshooting complex quality or regulatory issues
- Interpreting regulatory requirements for specific situations
- Advising on design trade-offs with regulatory implications
- Planning clinical or pre-clinical study approaches from quality perspective
- Developing corrective action strategies for major findings
- Organizational quality structure and role recommendations
- Strategic planning for scaling QMS as company grows
- Pre-submission meeting preparation and strategy
- Responding to FDA questions or audit observations
- Competitive regulatory landscape analysis

- Make/buy decisions for suppliers or components
- Contingency planning for regulatory or quality risks

All regulatory-related services are provided as needed based on availability and use of alternate regulatory resources.

Deliverables:

- Guidance and facilitation of all design control deliverables
- Audit-ready, controlled documentation with QA approval signatures
- QA review feedback with findings and corrections
- Updated SOPs and templates as needed
- Gap analysis and remediation plans
- Strategic guidance/feedback across quality, product development, and manufacturing areas (potential gaps, risks, courses of action)
- Risk mitigation strategies
- Submission readiness assessments from quality and operational perspectives
- Updated program roadmaps incorporating QMS development milestones
- Leadership support on key strategic and operational plans
- Organizational structure and process recommendations

Strategic Value:

- Ensures consistent quality oversight throughout development
- Adds leadership capacity to align operations and execution with strategy without the cost of a full-time hire
- Flexibility to increase or decrease commitment on a month-to-month basis based on development roadmap
- Supports and enables QMS and operational evolution based on scope of business activities
- Provides on-demand expertise for complex challenges without long term commitments
- Quickly reach vetted partners across other domains as needed throughout engagement, including in supplier quality, biocompatibility, supply chain, etc.

2. Startup QMS Implementation

Establish Quality Management System (QMS) suitable and adequate for initial phases of medical device development. The QMS package includes a standard operating procedure (SOP) for the following processes and the templates listed.

- **Design Controls**
  - Templates: Design and Development Plan, User Needs, System & Product Requirements, Design Review, Component Specification, Design History File (Medical Device File), Traceability Matrix
- **Control of Documents and Records**
  - Templates: General Document (Non-QMS), QMS Document, Change Order, Approval Matrix, Record
- **Risk Management**
  - Templates: Risk Management Plan, Hazard Analysis
- **Supplier Evaluation**
  - Templates: Supplier Evaluation Record, Audit Report, Supplier Quality Agreement
- **Quality Manual**
  - Templates: Organizational Structure
- **Comprehensive General Terms and Definitions** (definitions resource for medical device development)

Services Included:

- Configuring the QMS to align with roles and responsibilities for Conform team members. These configurations include:
  - On the Approval Matrix, entering appropriate approvers and roles for each document type based on roles and responsibilities of the Conform team.
  - Populate the Organizational Structure Template, identifying top management and respective authorities, and release to support the Quality Manual
- Initial release of QMS procedures and templates into document control system.

Strategic Value:

- Quickly start developing under your QMS after a rapid QMS implementation

3. Document Control Service Agreement

Establishes ISO 13485-compliant document control repository for Conform Medical following the requirements in the Control of Documents and Records process included in the QMS package.

Document and record control features include:

- Electronic storage and access to controlled documents with no storage limits
- 21 CFR Part 11-compliant electronic approval
- Document version control and traceability
- Support for large file uploads and storage
- HIPPA and SOC 1/2/3 compliance support, if required
- Data loss protection and security monitoring

Services Included:

Base Service includes:

- Reoccurring fees for associated software, i.e. 21 CFR Part 11 approval software for GxP compliance, are included for up to 10 users.
- Initial and ongoing user access administration and validation services
- Reserves availability and support for document control services..

Document control hourly support includes:

- Receiving and processing document and record change requests (design specifications, etc)
- Routing documents through approval workflows
- Managing document releases and tracking status
- Email/message-based coordination for document routing and status updates
- Maintaining document control records

Strategic Value:

- No separate eQMS contract or software procurement needed
- No internal infrastructure for compliant document management
- Immediate access to regulatory-compliant document control
- Scalable system that grows with your needs