Navigating the Path to ISO 13485 Certification with Red Medtech

At Red Medtech, we understand that achieving ISO 13485 certification is a significant milestone for medical device organizations. It signifies your commitment to quality and regulatory compliance, essential for ensuring the safety and effectiveness of your products. To help you on this journey, we offer comprehensive consulting services tailored to your specific needs. Here's what you can expect when you embark on the path to ISO 13485 certification with us:

Understand: Consulting

Medical device organizations must possess the knowledge, skills, and capabilities to support a Quality Management System (QMS) beyond the certification process. Red Medtech offers flexible consulting solutions, including project-based or subscription month retainer options, to empower your team with the expertise needed to thrive in the post-certification environment.

Prepare: Gap Analysis

Our gap analysis is a critical starting point. It reveals the "gaps" between your current state and the desired operational state compliant with ISO 13485. This analysis provides a roadmap for the steps required to bridge these gaps effectively.

Implement: Internal Audits

Effective internal audits are essential and must be conducted against the requirements of the ISO 13485 Quality Management System standard. Red Medtech engage our in-house Notified Body trained Lead Auditors to conduct rigorous internal audits aligned with ISO 13485,ensuring your processes and procedures meet the required standards.

Quality: Document Development

We assist you in reviewing your existing policies and procedures, aligning them with ISO 13485 standards. This involves a comprehensive examination and necessary modifications to ensure compliance with the standard.

Review: Implementation

Continuous monitoring is vital to ensure team members embrace the new QMS procedures, processes and documentation requirements seamlessly. Red Medtech oversees this phase to maintain the effectiveness of your QMS.

Evidencing: Internal Audit

Planning and conducting your internal audits demonstrates that you meet the requirements of the standard and ensures the continued effectiveness of your processes and procedures, addressing any emerging issues promptly.

Documented: Management Review

We can engage with your senior management to evaluate the effectiveness of your management system. This dialogue identifies strengths and weaknesses, facilitating ongoing improvements. We conduct an appraisal of your documented Management Reviews procedures and records to ensure adequacy and effectiveness.

Evaluate: Pre-assessment

Before the formal certification process starts, a pre-assessment audit is conducted to identify areas that require further attention. This exercise helps prepare key team members and refine your system, ensuring a smoother formal audit process.

Stage 1 Assessment: Document Review - Desktop

We perform a comprehensive review of your documented QMS processes and procedures to assess their suitability and readiness for the Stage 2 Assessment. Following this evaluation, we provide a comprehensive assessment report and recommendations.

Stage 2 Assessment: Hybrid - Desktop/On-site Visit

This stage determines whether your implemented system conforms to the ISO 13485 standard. Certification depends on management review and approval of the report, as well as the Lead Reviewer's recommendation. Minor non-conformities, if identified, will not prevent certification as long as a satisfactory corrective action plan is in place. A major non-conformity will likely result in a delay and must be closed out to within the timeframe to allow a recommendation for certification.

Minor NC: Non-fulfilment that DOES NOT affect ability of QMS to achieve intended results
Major NC: Non-fulfilment DOES affect QMS to achieve intended results

Promote: Certificate Issue

Upon successful completion, your selected certification body will award your organization the ISO 13485 certificate in recognition of your achievement. You can proudly display any associated Assurance Marks to showcase your certification to stakeholders.

Maintain: Continuing Assessment Visit

Your certification body will conduct routine assessments to evaluate the ongoing performance of your systems. After each assessment, you'll receive a detailed report.

Certificate: Reassessment

Re-certification is required every three years after the initial certification. It involves a comprehensive review of the entire system. In cases where significant issues have arisen during the certification cycle, additional reviews may be conducted to ensure continuous compliance.

Red Medtech is your trusted partner on the path to ISO 13485 certification. We are dedicated to supporting your organization's success and helping you maintain the highest standards of quality in the medical device industry. Contact us today to begin your journey towards ISO 13485 certification excellence.

Contact us now to discuss your regulatory compliance needs.

Prof. **Laurie Rowe** BSc IEng MIED MIET MIPEM MWES CIlr

Founder & Director, Medical Device Consultant

+44 (0) 1267 243388 Red Brochure

Book a meeting to disucss your project