ISO 13485:2016

ISO 13485 is the most widely recognized framework for medical device manufacturers, designers, and suppliers to demonstrate compliance to regulatory requirements, mitigate risks, and ensure best practices for quality, safety, and sustainability. Compliance to the standard provides a suitable, adequate and effective quality management system (QMS) for worldwide markets.

TIMELINE

The new version of the standard, ISO 13485:2016, was published March 1, 2016. Certification for organizations to ISO 13485:2003 will expire March 1, 2019 and those seeking a new certification or recertification after March 1, 2018 must meet the requirement of the 2016 edition.

NEW FOCUS

Significant changes to the ISO 13485 standard include

- Explicit requirements to implement the risk based approach
- Increased attention on supplier management processes
- Greater focus on post-market surveillance
- Requirements for validation of QMS software
- Increased alignment with global regulatory requirements

R&Q CAN HELP

R&Q can support your transition from ISO 13485:2003 to ISO 13485:2016 with strategic planning to hands-on support. Our services deliver business-balanced solutions that are right for your business. Our services include:

- **Gap Assessment**
  An assessment to determine changes needed to your quality management system to meet the requirements of ISO 13485:2016.
- **Internal/mock Audit**
  Develop an audit plan, perform an internal audit and prepare an audit report for compliance with the requirements of ISO 13485:2016 and your quality management system for each facility.
- **QMS Processes**
  Provide quality management systems guidance and assist in the development of a quality management system processes and work instructions based on requirements of ISO 13485:2016.
- **QMS Training**
  Onsite training including: Interactive overview of implementation and auditing to ISO 13485: 2016; Significant changes between ISO 13485: 2003 and ISO 13485: 2016; and How to utilize a risk-based approach for QMS development.

ISO 13485:2016

R&Q is a diverse supplier.

Certified WBENC Women's Business Enterprise

WHY R&Q?

R&Q exists to help you bring more safe and effective medical devices to market. Leveraging our deep industry experience, we provide solutions that help you improve the world. Drawing on our expertise across the entire medical device product lifecycle, we are uniquely positioned to present a range of strategic and tactical options and execute on the solution that best suits your individual regulatory and quality needs.

REGULATORY

Worldwide Regulatory Strategy, 510(k), PMA
EU and Canadian Entrance
Rest-of-World Support
UDI Compliance
Regulatory Counsel
Acquisition Regulatory Due Diligence

QUALITY SYSTEMS

Quality System Development
(ISO13485/QSR/CMDR)
Internal Auditing
FDA Inspection Preparedness/Assistance
Quality System Improvement Projects
Acquisition Integration

DESIGN ASSURANCE

Design Quality Assurance and Engineering
(Software, Electromechanical, Disposables)
Design Verification and Validation
Human Factors/Usability
Safety Risk Management

PRODUCT QUALITY

Supplier Quality and Audits
Process Validation/Qualification
Manufacturing Site Transfer
Manufacturing Quality Process

POST-MARKET SURVEILLANCE

Form 483, Warning Letter, Consent Decree
Strategy and Remediation Support
CAPA and Complaint Monitoring/Leadership
Safety Risk Monitoring
Recall Decisions
Design History File

REMEDIATION

Proactive and Reactive
Best Practice Strategic and Tactical Solutions
Gap Assessment and Process Improvement
Hands-on Guidance for Optimizing Quality Systems
Project Team Assembly
Root Cause Analysis and Corrective Action

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