ISO 13485

QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES

DQS MANAGEMENT SYSTEMS SOLUTIONS | 1500 MCCONNOR PARKWAY SUITE 400 | SCHAUMBURG, IL 60173 | 800-285-4476 | WWW.DQSUS.COM

Other Audit, Inspection and Certification Services Offered by DQS:

- European Directive -- Medical Devices Directive
- MDSAP--MedicalDevicesSingleAudit Programs
- AuditOne--AuditandCertification Services
- ISO27001fortheHealthcareIndustry --InformationSecurityManagement Systems
- ISO 14971 -- Risk Management for Medical Devices
- ISO 15378 -- Quality Management Systems for Medicinal Packaging Material Suppliers
- As well as other management systems, audits, and certification services including AS 9100, IATF 16949, ISO 9001, and ISO 14001. To see the entire list please visit www.dqsus.com

DQS is your global ISO 13485:2016 certification body solution for quality management systems (QMS) and regulatory certifications for finished medical device and component manufacturers, contract manufacturers, and providers of support services within the global medical device and life science industry.

Regardless of your organization's activities within the industry, the introduction of the revised ISO 13485:2016 International Standard is relevant. ISO 13485:2016 is intended to apply to organizations who serve in a variety of roles within the supply chain for medical devices.

The structure of ISO 13485:2016 is similar to the previous versions, and the changes provide more emphasis on applying a risk-based approach to the control of the processes needed for the QMS as well as clarified existing requirements and added additional conditions for satisfying quality and regulatory requirements.

What Type of Organizations are eligible for ISO 13485 Certification?

As a finished medical device manufacturer and/or legal entity intending to sell and place medical devices in the global market, an essential part of the process is having a certified QMS satisfying the quality and regulatory compliance requirements of ISO 13485.

However, more and more in today's industry, medical device manufacturers, designers and developers are outsourcing processes to contract manufacturers, suppliers and other service providers. To ensure more effective management and control of critical outsourced processes, medical device organizations are requiring their supply chain service providers to also be ISO 13485 certified as a basis for doing business with them.

See Reverse Side for Expanded List of the Types of Organizations Who Would Benefit from ISO 13485 Certification

What Types of Organizations are Eligible to Obtain ISO 13485 Certification?

- Legal Manufacturers (responsible for gaining market access and placing the finished medical devices on the market
- Private Labelers and Kitters of Finished Medical Devices
- Organizations Performing the Following Functions:
  - Design and/or Development
  - Manufacturing and/or Production
  - Storage and/or Distribution
  - Installation and/or Service and/or Repair and/or Refurbishing and/or Remanufacturing
  - Final Decommissioning and/or Disposal of Medical Devices
  - As well as Providers of Associated Activities and/or Processes (e.g., Technical Support)
  - Provider Organizations Involved in the Life-Cycle of Medical Devices
- Organizations Who Provide or Perform on Behalf of the Medical Device Organizations as an Outsourced Service Provider of the Following:
  - Raw Materials Used in Medical Devices
  - Components Used in Medical Devices
  - Sub-Assemblies Used in Medical Devices
  - Assembly of Finished Medical Devices in Accordance with the Customer's Specified Requirements
  - Sterilization Services
  - Packaging Services
  - Calibration Services
  - Distribution Services
  - Maintenance Services
  - Engineering and/or Consulting Support Services

Why Select DQS Inc. For Your ISO 13485 Audit and Certification Service Needs?

DQS Inc. is part of the global DQS Group of companies. We are a globally recognized brand with over 80 offices in 60 countries. Working in close collaboration with DQS-MED GmbH, DQS Inc., is a reliable partner offering audits, certifications, and other global market access services to organizations that operate within or provides services to the medical device and life science industry sectors. DQS Inc.'s ANAB accreditation applies to ISO 13485, ISO 9001 and other Management Standards. Additionally, DQS Inc. can provide services through DQS-MED which is a well-established Notified Body (CE 0297) under the scope of the European Medical Devices Directive (93/42/EEC) and is accredited to ISO 13485 (SCC and DAkkS) as well as recognized as an Auditing Organization (AO) by the MDSAP Regulatory Authorities Council.