ISO 13485 Management System For Medical Devices (MDQMS)

Introduction:

ISO 13485 is the most widely used for medical devices throughout the world; it shapes the quality management systems for medical device manufacturers globally; it applies to design, development, production, installation and servicing of medical devices. This international standard drives customers and competitors to take quality seriously in medical devices design, research, development, and manufacturing. ISO 13485 and compliance is a measure of the ability to meet customer and legal requirements. This course is designed to provide participants with the knowledge to assist their companies in getting products to market more quickly. ISO 13485 was written to support medical device manufacturers in designing quality management systems that establish and maintain the effectiveness of their processes. It ensures the consistent design, development, production, installation, and delivery of medical devices that are safe for their intended purpose.

Who Should Attend?

Managers, Team Leaders, Line Managers, Superintendents, OE Champions, Quality and Project Managers, Supervisors, Executives, Internal and External Auditors, Members of IT Team, Health & Safety Managers, Risk Managers, Business Process Owners, Business Finance Managers, Business Risk Managers, Regulatory Compliance Managers, Project Managers, Continuity, Risk, Quality, IT and Environmental Managers, Anyone involved in the system development, implementation and maintenance, Regulatory Affairs Managers, Consultants, Anyone who is involved in

ISO standards, Anyone involved in defining, planning, or implementing an ISO 13485 based quality management system, Anyone involved in the medical field, Professionals from the medical device industry wanting to gain a comprehensive knowledge of the main processes of MDQMS, Staff involved in the implementation of the ISO 13485 standard, Expert advisors in quality management for the medical device industry, Managers responsible for implementing MDQMS

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a QMS. Adopting ISO 13485 provides a practical foundation for manufacturers to address the Medical Device Directives, regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices. ISO 13485 is a stand-alone QMS standard, derived from the internationally recognized and accepted ISO 9000 quality management standard series. ISO 13485 adapts the ISO 9000 process-based model for a regulated medical device manufacturing environment. While ISO 13485 is based on the ISO 9001 process model concepts of Plan, Do, Check, Act, it is designed for regulatory compliance. It is more prescriptive in nature and requires a more thoroughly documented quality management system. This course enables participants to learn about the best practices for implementing and managing medical devices quality management system (MDQMS) as specified in ISO 13485:2016. The participant will learn the different components of a MDQMS such as quality manual, required procedures, records, measuring performance, management commitment, internal audit, management review and maintaining effectiveness. You will be able to:

- Use ISO 13485:2016 as the basis for a QMS for medical device manufacturers
- Understand the relationship between ISO 13485:2016 and European Medical Device Directives
- Use ISO 13485:2016 as the basis of regulatory requirements worldwide
- Take the first steps towards ISO 13485:2016 certification
- Understand how you can better meet customer and regulatory requirements leading to increased patientsafety
- Find ways to increase efficiency and cost savings through quality management
- Monitor supply chains to achieve continuous improvement
- Develop safe and effective medical devices
- Motivate employees through CPD

Course Objective

By the end of this course, delegates will be able to:

- Understand the fundamentals of quality management and medical devices
- Know the interrelationships between ISO 13485 and other related standards
- Know the key components of medical devices quality management system (MDQMS) in accordance with ISO 13485
- Introduce the concepts, approaches, standards, methods and techniques allowing to effectively manage MDQMS

- Understand the relationship between medical devices quality management system and compliance with customer and regulatory requirements
- Understand the stages of the ISO 13485 certification process
- Understand the importance of ISO 13485 on an international scale
- Differentiate between ISO 13485 and ISO 9001
- Get to grips with the different elements of ISO 13485 and ISO 14969
- Be familiar with the relationship between ISO 13485 and ISO 14971
- Define ISO 13485 management roles and responsibilities
- Increase access to more markets worldwide with certification
- Outline how to review and improve processes across your organization
- Increase efficiency, cut costs and monitor supply chain performance
- Demonstrate that you produce safer and more effective medical devices
- Meet regulatory requirements and customer expectations

Course Outline:

- Objectives of the initiative
- Introduction to medical devices quality management system (QMS) concepts as required by ISO 13485
- Normative frameworks and methodologies related to quality and medical devices
- Fundamental principles of quality and medical devices
- ISO 13485 certification process
- Detailed presentation of the clauses 4 to 8 of ISO 13485
- Planning and Initiating an ISO 13485 audit
- Fundamental audit concepts and principles
- Audit approach based on evidence
- Preparation of an ISO 13485 certification audit
- MDQMS documentation audit
- Conducting an opening meeting
- The challenge for top management
- Explain the structure and scope of the ISO 13485 management system standard
- How ISO 13485 applies to the organization aiming for regulatory compliance worldwide
- Compare the requirements between ISO 13485 and ISO 9001
- Describe the implementation process
- Produce a project plan for implementation
- Identify and justify the resources required for implementation
- Eight quality management principles
- Overview of ISO 13485:2003 requirements
- Overview of ISO 13485:2003 requirements – Clause 4
- Overview of ISO 13485:2003 requirements – Clause 5

- Overview of ISO 13485:2003 requirements – Clause 6
- Overview of ISO 13485:2003 requirements – Clause 7
- Overview of ISO 13485:2003 requirements – Clause 8
- Facilitate development of processes, policies, objectives, documentation and measurement techniques
- Prepare for ISO 13485 certification
- Interpret the clauses of ISO 13485 using ISO 14969:2005
- Recognize the role and responsibilities of management in ISO 13485
- Recognize the relationship between ISO 13485 and ISO 14971
- Appreciate the use of ISO 13485 as the basis of Medical Device Regulations worldwide
- Introduction to ISO 13485:2003 audit trails
- The relationship of risk classification of medical devices to QMS requirements
- Risk classification rules
- Risk classification names
- Using accredited ISO 13485 certification in practice
- Communication between stakeholders
- Communication during the audit
- Audit procedures: observation, document review, interview, sampling techniques, technical verification, corroboration and evaluation
- Audit test plans
- Formulation of audit findings
- Documenting nonconformities