MiChem Dynamics
LEADING CHANGE

ISO 13485:2016 MEDICAL DEVICES - QUALITY MANAGEMENT SYSTEM IMPLEMENTATION TRAINING

The ISO 13485:2016 Quality Management System (QMS) Implementation Training is a comprehensive program designed to provide participants with the knowledge and skills necessary to establish, implement, and maintain a quality management system in compliance with ISO 13485:2016 standards for medical devices.

This course is ideal for professionals involved in the design, development, manufacturing, and distribution of medical devices. Participants will leave the training with a comprehensive understanding of the standard and the practical tools needed for successful QMS implementation in their organizations, fostering a culture of quality, safety, and compliance in the medical device industry.

THE COURSE WILL RUN OVER A PERIOD OF 3 DAYS

LEARNING OUTCOMES:

- Understand the underlying structure of ISO 13485:2016 and all elements of a Quality Management System.
- Write their own Quality manual policies and procedures in compliance with ISO 13485:2016.
- Develop organisation competency and prepare for external certification audits.
- Identify relevant performance monitoring approaches.
- Continually improve data quality and effectiveness.
- Understand the importance of internal auditing, corrective actions and risk assessments.

WHO SHOULD ATTEND THIS COURSE:

- Quality assurance specialists / engineers
- Project managers
- Anyone involved in the development, maintenance or improvement of a quality management system

MINIMUM ENTRY REQUIREMENTS:

- Fluency in English writing and reading skills

TUITION:

- Training material included (English)
- Certificate of attendance or competence (based on outcome of assessment) will be issued on successful completion of training.

santie@michemdynamics.co.za | angeline@michemdynamics.co.za | 082 770 7127 or 078 335 0528
www.michemdynamics.co.za

COURSE OVERVIEW:

DAY 1

- Introduction
- ISO 13485 Clause 4 Quality management system
  - General requirements
  - Documentation requirements
- ISO 13485 Clause 5 Management responsibility
  - Management commitment
  - Customer focus
  - Quality policy
  - Planning
  - Responsibility, authority and communication
  - Management review
- ISO 13485 Clause 6 Resource requirements
  - Provision of resources
  - Human resources
  - Infrastructure
  - Work environment and contamination control

DAY 2

- ISO 13485 Clause 7 Product realization
  - Planning of product realization
  - Customer-related processes
  - Design and development
  - Purchasing
  - Production and service provision
  - Control of monitoring and measuring equipment

DAY 3

- ISO 13485 Clause 8 Measurement, analysis and improvement
  - General
  - Monitoring and measurement
  - Control of nonconforming product
  - Analysis of data
  - Improvement
- Test (assessment)

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