

For those who are:

Implementing a Quality Management System.

Quality Management System auditors.

Quality Engineers or Regulatory Affairs professionals.

Benefits of the Course

Highly skilled tutor with Notified Body (CE) and Competent Authority (SFDA) experience.

Practical, to incite discussion and accelerate learning.

Provides an open forum to air concerns and ask questions.

Offers the opportunity to compare notes and interact with industry peers.

A full set of course notes and guidance documents for post-course referral.

Three x 2½ hour modules held live in an on-line lecture theatre
Introduction to ISO 13485: Clause by Clause



Goals of the Course

1. Introduction and the QMS

Legal Framework & Z Annexes.
Terms & Definitions.
Top Level QMS.
Procedures.
Documents and Records.

2. Plan

Principles of Plan, Do, Check, Act.
Resource Management.

Do

Sales.
Purchasing.
Design.
Manufacture.

3. Check

Post-Market Feedback.
Internal Audit.
Non-conforming Product.
Analysis.
Handling Non-conformities.

Act

Management Responsibility.
Quality & Objectives.
Management Review.

Courses

Public course dates available.

All private courses tailored to the client's individual devices.

Hotel and parking at special rates.

The Academy Centre

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المؤسسة العامة للتدريب التقني والمهني
Technical and Vocational Training Corporation



Course code
OC0503