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For those who are:

Implementing audits as a manufacturer, importer or distributor.

Involved in Quality Systems for the Saudi Regulation on Medical Devices and IVDs.

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.

Five x 2½ hour modules held live in an on-line lecture theatre

Internal Auditor for ISO 13485

Academy Centre

Goals of the Course

1. Introduction
First, second & third party audits.
Audit activities.
Audit types.
Audit methods.

2. Principles of Auditing
Objectives, scope and criteria.
Roles and responsibilities.
Management.
Confidentiality.
Communication.

3. Planning an Audit
Purpose of a Quality Management System.
Plan, do, check, act.
Process auditing.
Document types.
Exclusions and non-applications.
Audit plan.

4. Audit Techniques
Work documents and checklists.
Opening meeting.
Audit evidence.
Observations.
Audit trails.
Audit meetings.
Non-conformities.
Closing meeting.

5. Reports and Follow-up
Audit report.
Corrective action plans.
Audit follow-up.

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
OC0605