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For those who are:

Implementing the Saudi Regulation on Medical Devices and IVDs.

Involved in writing technical files or 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.

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

The Saudi Regulation for Medical Devices and IVDs

Academy Centre

Goals of the Course

1. Introduction
Scope of the law & assessment.
Medical device definitions.
State of the art.

Identifying devices.
Borderline devices.

2. Classification and Subcontractors
Classification and rules.
Subcontractors.
Device specification.

3. EPs and V&V
Essential Principles checklist.
Verification and Validation.

4. Risk
Legal requirements
Hazard analysis

5. Clinical
Clinical Evaluation Plan.
Equivalence.
Literature review.
Clinical Evaluation Report.

6. Post Market Surveillance
Declaration of conformity.
Post Market Clinical Follow-up.
Post Market Surveillance.
Periodic Safety Update Report.

7. Vigilance and Technical File.
Conducting vigilance.
Risk/benefit
Technical file construction

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
OC0107