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For those who are:

Implementing the EU In Vitro Medical Device Regulation in their organisation.

Involved in writing Technical Files or Quality Systems for the EU In Vitro Medical Device Regulation.

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

In Vitro Medical Device Regulation (EU) 2017/746

Academy Centre

Goals of the Course

1. Introduction
Definitions & Application.
Manufacturing Articles.
Other economic operators.

2. DoC & Classification
Declaration of Conformity.
Rules for Classification.
Unique Device Identification.

3. GSPRs & Risk
The GSPRs.
Hazard Analysis.
Risk Analysis.

4. Performance Evaluation
Performance Evaluation Plan.
Performance Evaluation Report.

5. Post Market Activities
Post-Market Surveillance & Clinical Follow-up.
Periodic Safety Update Report & SSP.
Vigilance.

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
OC0405