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For those who are:

Implementing the EU Medical Device Regulation in their organisation.

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

Quality Engineers or Regulatory Affairs professionals.

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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.

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

Medical Device Regulation (EU) 2017/745

Academy Centre

Goals of the Course

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

2. Other articles
Declaration of Conformity.
Unique Device Identification.
Eudamed.

3. Classification & Conformity
Rules for Classification.
Article 52.
Annex IX, X & XI.

4. Risk
Hazard Analysis.
Risk Analysis.

5. GSPRs
The GSPRs.
Verification and Validation.
Labelling and Instructions for Use.
Technical File Requirements.

6. Clinical Evaluation
Clinical Evaluation Plan.
Clinical Evaluation Report.

7. Post Market
Post-Market Surveillance & Clinical Follow-up.
Periodic Safety Update Report & SSCP.
Vigilance.

8. Compliance
Technical File.
Transition.
Questions.

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
OC0308