

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.

Eight x 2½ hour modules held live in an on-line lecture theatre
In Vitro Medical Device Regulation (EU) 2017/746



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 54.
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. Performance Evaluation

Performance Evaluation Plan.
Performance Evaluation Report.

7. Post Market

Post-Market Surveillance &
Performance 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
OC0408