SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

Regulatory Requirements for Importers and Distributors of Medical Devices, EU MDR 2017/745

LS049

Regulatory Requirements for Importers and Distributors of Medical Devices, EU MDR 2017/745

The EU Medical Device Regulation (EU MDR 2017/745) has introduced significant new legal responsibilities for organisations that import or distribute medical devices into the European Union.

For many businesses, these requirements are new, detailed, and often unexpected. Many importers are only now becoming aware that they carry direct legal accountability for device compliance when they place a medical device from outside the EU onto the union market.

Competent Authorities across the EU, including the HPRA in Ireland, are actively inspecting organisations to verify compliance. These inspections have highlighted a common misunderstanding. Importing was previously viewed as a logistics activity. Under EU MDR, it is a regulated legal role.

Importers and distributors must now verify device documentation, confirm correct CE marking, review Declarations of Conformity, check labelling requirements, maintain full traceability, recognise potentially falsified devices, and meet the defined obligations set out in Articles 13 and 14 of the Regulation.

This one-day programme gives participants a structured, practical understanding of the key MDR requirements that apply specifically to Importers and Distributors. The content is grounded in real examples and challenges observed during HPRA inspections and industry support work, helping learners connect the legislation to real operational decisions.

Throughout the day, participants work through practical documentation and scenarios to build confidence in applying requirements correctly and strengthening their organisation’s ability to demonstrate conformity under EU MDR.

It is designed to build confidence, remove uncertainty, and help organisations understand exactly where they stand.

Duration & Price

Duration: 1 day
Public Virtual Training: €425
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
24 Sep 2026	Virtual	Book Date

In-Company Training

Please contact us for more information on our In-Company training options

What's covered?

The programme covers the core MDR requirements that apply specifically to importers and distributors, focusing on the practical checks, documentation, and responsibilities outlined in Articles 13 and 14. Before exploring each requirement in detail, the section clarifies the roles within the EU supply chain and highlights the key elements organisations must verify to demonstrate compliance.

- Overview of EU MDR 2017/745: structure, purpose, and regulatory context
- Medical device definition and examples of borderline products
- EU supply chain roles: Manufacturer, Authorised Representative, Importer, Distributor
- Article 13 (Importers): detailed obligations and required documentation checks
- Article 14 (Distributors): verification responsibilities and practical compliance checks
- Understanding and verifying CE marking & Declarations of Conformity
- EUDAMED importer registration requirements and timelines
- UDI, device traceability, and supply?chain documentation expectations
- Device labelling, packaging, and recognised symbols, including environmental conditions and sterilisation indicators
- Identifying falsified devices
- Responsibilities in reporting complaints, incidents, and serious incidents to manufacturers and Competent Authorities (post-market surveillance (PMS) and vigilance)

Who should participate?

This programme is suitable for individuals and teams involved in importing or distributing medical devices, including:

- Quality and Regulatory personnel
- Warehouse, stores, and goods?in teams
- Procurement and supply?chain personnel
- Internal and external auditors
- Senior management with responsibility for compliance or operational oversight

It is also applicable to medical device manufacturers who import or distribute devices as part of their business model.

What will I learn?

This programme gives participants a clear understanding of the MDR responsibilities that apply to importers and distributors. It first clarifies what qualifies as a medical device and how organisations fall into importer or distributor roles, before exploring the specific obligations under Articles 13 and 14. Learners gain the practical knowledge needed to apply these requirements confidently in their day to day operations.

- By completing this programme, participants will be able to:
- Understand the purpose of the EU MDR and how it affects importers and distributors.
- Identify whether a product is a medical device, based on its intended purpose and associated risks.
- Explain the legal responsibilities of importers and distributors under Articles 13 and 14.
- Perform the required checks on CE marking, device labelling, authorised representatives, and declarations.
- Recognise signs of falsified devices and understand appropriate actions.
- Understand traceability obligations and how to maintain supply chain transparency.
- Identify key medical device symbols including storage, environmental, and manufacturer/importer markings.
- Understand the importance of correct storage, transport, and environmental requirements for devices under your control
- Appreciate the role and requirements of UDI and EUDAMED importer registrations.

How do we train and support you?

The programme is delivered by Anne Marie Newell, she has extensive practical knowledge of MDR implementation, HPRA inspections, and real?world importer/distributor challenges. Anne Marie encourages discussion, uses practical examples, and helps participants understand how to apply MDR requirements within their own operations.

For In?Company delivery, we can incorporate organisation?specific examples such as device labels, IFUs, Declarations of Conformity, and real audit findings to strengthen learning and relevance.

Tutors

Anne Marie Newell
View Profile

What Our Learners Say

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