



TRAINING COURSE

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES

Date: 29 – 30 April 2021
Time: 9:00 – 14:00
Venue: Online event

A two-day interactive online training course organized by the Malta Laboratories Network bringing together experts in the field and participants to exchange knowledge and network together.

Benefits of the course

This training course provides knowledge about changes in EU regulations and their impact on practice. Participants will understand the key safety and quality requirements, their control and assessment. The course discusses innovation within traceability of medical devices, field safety corrective actions and incidence reporting.

Learning objectives

By the end of the course, the participants will be able to:

- i. Understand what medical devices are and the need for quality, safety and proven performance of medical devices
- ii. Describe regulations of medical devices
- iii. Understand definitions used and classifications of medical devices and in vitro diagnostic medical devices (IVD)
- iv. Acknowledge how to deal with applicability of ISO standards, complaints and noncompliance
- v. Communicate the responsibility for medical devices safety and performance
- vi. Define CE markings and conformity assessments
- vii. Discuss EUDAMED function and structure
- viii. Understand the key requirements and concepts of the post-marketing surveillance and vigilance under the MDR and IVDR

Who should attend?

Target audience:

- ✓ Distributors, importers, manufacturers, retailers
- ✓ Healthcare professionals
- ✓ Patient advocates: carers, users, managers
- ✓ Scientists, technologists and technicians with interest in medical devices
- ✓ Regulatory professionals and other personnel
- ✓ Professionals from the legal field
- ✓ Procurement personnel
- ✓ Stakeholders with an interest in medical devices industry and business

Registration and Payment

Course fee: 400 Euro for one participant
 600 Euro for two participants from the same organization
 700 Euro for three participants from the same organization

Register on the link <https://forms.gle/w7b3mkxVyS1BVGiz7> by not later than 16 April 2021.

Registration will only be confirmed once payment is received.

You are kindly requested to send the proof of payment and indicate name of attendee/s to info.mln@gov.mt and silvana.b.camilleri@gov.mt

For further queries, please contact us on: info.mln@gov.mt

Certificate of participation will be awarded to participants.