

Award in Medical Devices (Level 5 MQF/EQF, 1ECTS)

A three-day interactive training course organised through a collaborative initiative between the Malta Laboratories Network and the Medical Devices and Pharmaceutical Collaboration Directorate at the Malta Medicines Authority.

Benefits of the course

Medical devices and in-vitro diagnostic devices are intended for medical use and some can pose a significant risk for a patient, therefore their regulation and assessment are of utmost importance. This training course will provide essential knowledge about changes in EU regulations and their impact on a practice. Participants will understand the key safety and quality requirements, their control and assessment. This course will provide clear guidance on traceability of medical devices, field safety corrective actions and incident reporting.

Learning objectives

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

- i. Describe regulations of medical devices;
- ii. Understand definitions used and classifications of medical devices and in-vitro diagnostic medical devices (IVDs);
- iii. Acknowledge quality and safety requirements of medical devices and applicability of ISO standards;
- iv. Communicate the responsibility for medical devices safety and performance;
- v. Define CE markings and conformity assessments;
- vi. Discuss EUDAMED function and structure;
- vii. Understand the key requirements and concepts of 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 the medical device industry and business

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

Award in Medical Devices is accredited and recognised by the Malta Further and Higher Education Authority. Awards will be granted to participants who successfully complete the course.

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