

MALTA

MEDICINES
AUTHORITY



ACADEMY
FOR PATIENT CENTRED
EXCELLENCE AND INNOVATION
IN REGULATORY SCIENCES

Award in Medical Devices

Award in Medical Devices

A course organised by the MMA Academy, intended to convey solid theoretical grounding in tandem with practice-oriented implementation of key principles and requirements emanating from the recently established European Medical Device and In-Vitro Diagnostic Regulations along with recognised standards and guidelines. It endeavours to provide a networking forum for the dissemination of scientific acumen and best practices, steering the translation of pertinent provisions into day-to-day excellence and high-quality healthcare solutions.

MQF Level: 5

ECTS: 1

Dates: 30 November - 1 December 2021 - Virtual Live Sessions

2 December 2021 - Face-to-Face Sessions at Malta Life Sciences Park, San Ġwann
(full days for a total of 25 hours)

Speakers:

Mr Piero Costa - A British Standards Institution (BSI) Tutor and Adjunct Professor at "Politecnico di Torino" who holds wide-ranging expertise and experience in the medical device industry acquired over years of professional activity.

Mr Julian Fearne - Head, Medical Device Unit, Malta Medicines Authority

Ms Karen Farrugia - Senior Pharmacist, Medical Device Unit, Malta Medicines Authority

Ms Lara Giudice - Senior Pharmacist, Medical Device Unit, Malta Medicines Authority

Objectives and learning outcomes:

A comprehensive overview of key concepts and requirements stemming from MDR 2017/745, IVDR 2017/746, alongside recognised standards and guidelines shall enable participants to:

- a) Interpret the legislative framework for medical devices and relevant terminology.
- b) Classify medical devices and identify applicable safety and performance requirements.
- c) Expand knowledge on Technical Documentation, risk management process, conformity assessment procedure, Declaration of Conformity, CE marking, advertising, labelling and Instructions for Use.
- d) Recall the importance of the Unique Device Identification (UDI) System and describe the structure and role of the European Databank on Medical Devices (EUDAMED).
- e) Recognise the importance of Quality Management Systems for medical devices, including applicability of ISO 13485:2016.
- f) Grasp Post-market Surveillance and Vigilance obligations from a distributor/importer perspective, including recalls, incident reporting, and field safety corrective actions.
- g) Discuss transition arrangements and national requirements.
- h) Convey concrete solutions to issues and formulate judgements in key areas of medical devices, supporting the transformation of potential challenges into opportunities.

Target Audience:

This course is directed at stakeholders, particularly distributors and importers, who are seeking to broaden their knowledge, skills and competences, enriching their expertise in the field of medical devices.

Entry Requirements:

Applicants are required to be in possession of qualification(s) at MQF Level 4 or higher. Mature students may be considered in line with the MMA Academy IQA Policy.

Delivery:

The blended learning approach encompassing interactive, remote learning sessions through an online platform in tandem with traditional face-to-face classroom-based training ensures the speakers and participants engage in discussions and debates, exchange ideas and collectively analyse evolving scenarios and prospective outcomes. Participants are enticed to think critically, collaborate, seek assistance through the appropriate channels and learn from peers, spearheading personal and professional growth and development in the learning process.

Assessment:

Formative feedback is provided throughout the course in response to effective questioning and engaging activities, emboldening dialogue and motivation, as well as knowledge recall, analytical thinking and evaluative skills. At the end of the course, participants shall complete a written summative assessment consistent with the stated learning objectives.

Certification:

Upon successful course completion, participants are granted an Award in Medical Devices accredited and recognised by the Malta Further and Higher Education Authority.

Course fee: €800

Registration:

Interested individuals are invited to read the [MMA Academy IQA Policy](#).

Registrations may be submitted via the [Online Registration Form](#) by not later than 12 November 2021.

For further information or assistance, kindly contact the MMA Academy via academy.medicinesauthority@gov.mt or 23439167/88.

