MALTA
MEDICINES
AUTHORITY

ACADEMY
FOR PATIENT CENTRED
EXCELLENCE AND INNOVATION
IN REGULATORY SCIENCES

Award in Medical Devices

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A Higher Education Programme accredited by the Malta Further and Higher Education Authority

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.

EQF/MQF Level: 5

ECTS: 1

Mode of attendance and Duration: Part-time for a total of 25 hours, including lectures (23 hours), self-study (1 hour) and assessment (1 hour)

Dates: 23 - 25 July 2024

Venue: Malta Life Sciences Park, San Ġwann

Speakers:

Mr. Piero Costa - A Biomedical Engineer, ISO 13485 Lead Auditor, Visiting Lecturer at 'Politecnico di Torino' and Team-PRRC Member and representative for Italy, who holds wide-ranging expertise and experience in the medical device industry acquired over years of professional activity.

Mr. Julian Fearne - Senior Head, Medical Devices, Medical Devices and Pharmaceutical Collaboration Directorate, Malta Medicines Authority

Dr Karen Farrugia – Head, Notified Bodies, Surveillance and Clinical Relations, Medical Devices and Pharmaceutical Collaboration Directorate, Malta Medicines Authority.

Learning Outcomes:

Competences

a. Ensure key requirements, concepts and obligations stipulated within EU MDR and IVDR are promptly understood, adhered to and implemented for conformity and enhanced patient safety.

b. Classify medical devices according to risk and monitoring required throughout their lifetime.

c. Select and apply conformity assessment procedures.

d. Implement safety and performance requirements.

e. Assemble Technical Documentation as per European Medical Device and In-Vitro Diagnostic Regulations.

f. Utilise the European Databank on Medical Devices (EUDAMED).

g. Interpret labelling supplied with the device.

h. Use ISO 13485:2016 as the basis for a Quality Management System.

i. Amend and maintain a Quality Management System.

j. Construe how post-marketing surveillance and vigilance processes integrate into the Quality Management System.

k. Collaborate with peers, exchange views and best practices, challenge assertions, convey concrete solutions and explore upshots within the medical device domain, supporting the transformation of potential challenges into opportunities.

l. Identify training needs within the medical device working field.

m. Exercise management, training and supervision in line with regulatory obligations to guarantee safety and efficacy of medical devices reaching consumers.

Knowledge

a. Interpret the legislative framework for medical devices.

b. Describe risk classification of medical devices.

c. Define conformity assessment and distinguish between different conformity assessment procedures.

d. Identify applicable safety and performance requirements.

e. Discern Technical Documentation requirements and transition arrangements.

f. Recall the importance of the Unique Device Identification (UDI) System

g. Describe the structure and role of the European Databank on Medical Devices (EUDAMED).

h. Appreciate the significance of the CE marking, labelling and Instructions for Use (IFU).

i. Grasp fundamental Post-market Surveillance and Vigilance concepts, including post-marketing follow up obligations, risks and threats posed by market infiltration of counterfeit and substandard products, recalls, incident reporting, and field safety corrective actions.

j. Recognise the importance of Quality Management Systems for medical devices, including applicability of ISO 13485:2016.

k. Convey concrete solutions to issues in key areas of medical devices, supporting the transformation of potential challenges into opportunities.

l. Formulate judgements regarding the medical devices' regulatory trajectory.

Skills

a. Actively apply key MDR and/or IVDR provisions, requirements and roles/ responsibilities in tandem with ISO principles into day-to-day practices.

b. Determine the regulatory course for a medical device as per EU MDR/IVDR.

c. Transform emerging challenges into opportunities.

d. Implement safety and performance requirements.

e. Convey key concepts and ideas effectively to colleagues and stakeholders using published regulations and guidelines.

Learning to Learn Skills

a. Spearhead personal and professional growth and development through initiative, inquisitiveness and informed choices.

b. Become a proactive leader in own learning process.

c. Recognise own strength while improving confidence to seek assistance through appropriate channels.

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.

For third country nationals, the link to Identity Malta's VISA requirement refers: https://www.identitymalta.com/unit/central-visa-unit/

Delivery:

This programme is delivered in the English Language. The Traditional/Face-to-Face Learning approach ensures that the speaker(s) and participants engage in discussions and debates, exchange ideas, and collectively analyze evolving scenarios and prospective outcomes. In tandem, 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:

At the end of the course, participants shall complete a written summative assessment consistent with the stated learning objectives.

Certification:

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

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 10 July 2024.

For further information or assistance, kindly contact the MMA Academy via academy.medicinesauthority@gov.mt or 23439188 or 23439280