ACADEMY
FOR PATIENT CENTRED EXCELLENCE AND INNOVATION IN REGULATORY SCIENCES

MALTA MEDICINES AUTHORITY

AWARD in MEDICAL DEVICES

23-25 July, 2024

Malta Life Sciences Park, San Ġwann

Speakers/Moderators:

Mr Piero Costa - Biomedical Engineer, ISO 13485 Lead Auditor
Mr Julian Fearne – Senior Head, Medical Devices, Medical Devices and Pharmaceutical Collaboration Directorate, MMA
Dr Karen Farrugia – Head, Notified Bodies, Surveillance and Clinical Relations, Medical Devices and Pharmaceutical Collaboration Directorate, MMA

Day 1	
08:45 – 09:00	Registration
09:00 – 11:00	Introduction to European legislation and general overview on the MDR/IVDR Scope of the MDR/IVDR Manufacturer/Distributor/Importer definitions & obligations
11:00 – 11:15	*Refreshment break*
11:15 – 13:15	Determining risk class of device Identifying applicable safety and performance requirements
13:15 – 13:45	*Lunch break*
13:45 – 15:45	Overview of Technical Documentation Risk Management Process Conformity assessment procedure
15:45 – 16:00	*Refreshment break*
16:00 – 18:00	Information to be provided by Manufacturers/Economic Operators Advertising, labelling & Instructions for Use (IFU) Declaration of Conformity (DoC) and CE marking
Day 2	
08:45 – 09:00	Registration
09:00 – 11:00	UDI-DI & EUDAMED Overview on ISO13485:2016, as applicable to distributors/importers
11:00 – 11:15	*Refreshment break*
11:15 – 13:15	Amending and maintaining a Quality Management System
13:15 – 13:45	*Lunch break*
13:45 – 15:45	Post Market Surveillance and Vigilance obligations from a distributor/importer point of view, including recalls, incident reporting, and field safety corrective actions
15:45 – 16:00	*Refreshment break*
16:00 – 18:00	Transition arrangements (derogation periods, grand-father clauses, functionality before EUDAMED go live date) Questions & Answers
Day 3	
08:45 – 09:00	Registration
09:00 – 11:00	Workshop A: Vigilance, recalls and Field Safety Corrective Action (FSCA)/Field Safety Notice (FSN) Workshop B: National Legislation including organisation registration and other national applications
11:00 – 11:15	*Refreshment break*
11:15 – 13:15	Workshop C: Inspections and Good Distribution Practice Workshop D: Updates in laws and regulations including timelines and extensions.
13:15 – 13:45	*Lunch Break*
13:45 – 14:45	Recapitulation of workshops and Q&A Session
14:45 – 15:45	Consolidation Session / Interactive discussion sessions with speakers
15:45 – 16:00	*Refreshment break*
16:00 – 17:00	Summative Assessment
17:00 – 18:00	Evaluation and Conclusion