European Medical Device Leadership: Advanced Training course –

29 - 30 October 2019

29th October 2019 – Introduction & Post-Marketing Surveillance

08:45 – 09:00	**Registration**
09:00 – 09:15	**Opening** Hon. Dr Deo Debattista *Parliamentary Secretary for Consumer Rights, Public Cleansing and Support for the Capital City* Prof Anthony Serracino Inglott *Chairperson, Malta Medicines Authority*
SESSION ONE - INTRODUCTION	
09:15 – 09.45	Medical devices classification and Drug- Device Combination products • *What are medical devices?* • *How are these classified?* • *What are drug-device combination products?*
Coffee Break	
10:00 – 11:30	Conformity assessments • *What are conformity assessments?* • *What are the objectives of the assessments?* • *What is the conformity assessment procedure?* • *What are the general safety & performance requirements?* • *What is the declaration of conformity?* • *What is ISO 13485?*
11:30 – 12:30	Medical device registration • *What are the labelling requirements?* • *What is UDI and what are the requirements?* • *What is EUDAMED?* • *What are the registration requirements in the MDR?* • *What are the requirements for distributors, importers and authorised representatives?*
12:30 – 12:45	Technological aspects of medical devices
12:45 – 13:00	Q & A
Lunch	
SESSION TWO – POST-MARKETING SURVEILLANCE	
14:00 – 14:30	Risk Management Plans • *What is Risk?* • *What are Risk Management Plans?* • *How to design a risk management plan?*
14:30 – 15:30	Incident reporting system
15:30 – 16:30	Field Safety Corrective Action
16:30 – 17:00	Round table discussion MAP, TOPRA and Manufacturer
17:00 – 17:15	Rapporteur – closing day remarks

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30th October 2019 – Medical Device Regulations & Parallel Sessions

08:45– 09:00	Registration
Session Three – Medical Device Regulations	
09:00 – 10:00	Medical Device EU Regulations • *Overview of the EU Regulations and changes* • *Impact on Manufacturers, Wholesale Distributors, Retail*
Coffee Break	
10:15 – 10:45	Malta Medical Device Regulations
10:45 – 11:00	Integrating research into regulation
11:00 – 12:00	In-Vitro Diagnostics • *What are IVDs?* • *How are they classified?* • *What is the Regulation and how does it differ from the IVD Directive?*
12:00 – 12:15	Pitfalls in In-Vitro Diagnostics: a clinician's perspective
12:15 – 12:30	Q & A
Lunch	
13:30 – 14:30	EU Pathways for Biomarker Based Companion Diagnostic Development for Patient Stratification
Parallel Sessions A & B:	
14:30 – 16:00	Session A: Traceability of Medical Devices
OR	
14:30 – 16:00	Session B: Notified bodies • *What are notified bodies?* • *How are they designated?* • *What are their responsibilities?* • *How does a manufacturer work with a notified body?* • *Current concerns with notified bodies and the MDR.* • *Notified body audits and technical reviews.* • *Summary of how to CE mark a medical device.*
16:00 – 16:30	Rapporteurs feedback
16:30 – 17.00	Course evaluation and closing