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IRELAND

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The Practical Implementation of EU Regulations for Medical Devices and in vitro Diagnostic Medical Devices

John Deavin

Webinar for members of EIPG in conjunction with PIER and University College Cork

Click here to register

Wednesday 3rd February 2021 at 17.00 CET (16.00 GMT)

About the Speaker

John Deavin began his career as an analyst and QP. He moved into Regulatory Affairs and as well as a wide variety of medicinal products, he has registered a range of medical devices including catheters, orthopaedic products, sutures, drug/device borderline and human tissue products. He has been a member of the ABPI Regulatory Group, the EFPIA working group of the European Vaccine Manufacturers Division, and EuropaBio's cells and tissues consultation working group with the European Commission. He is a lecturer at Imperial College, London on Biomedical Engineering and at Cranfield University on Medical Technology.

Overview of Webinar

- Current Medical Device Directives and timetable for transition to the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR), the proposed UK system.
- Scope and rationale of the MDR 2017/745 and IVDR 2017/746.
- The Role of the European Commission (EC), EUDAMED (IT system developed to implement the Regulations), the Competent Authorities and the Medical Device Coordination Group (MDCG), interactions between the Competent Authority, Notified Bodies and Manufacturers.
- Notified Bodies (NB), their designation, roles and interactions, Conformity Assessment, Quality Systems, the Notified Body Operations Group (NBOG).
- Classification of Devices, Commission guideline on classification, Borderline products.
- General Safety and Performance Requirements, use of standards, including standards hierarchy, Technical file, Design dossier, interaction with the Quality Management System, Device labelling and Identification Systems (UDI).
- Clinical Evaluation: Requirement for clinical investigations under the MDR and for performance evaluation and studies under the IVDR.
- Risk Management and Post Market Surveillance, Vigilance and market surveillance.

Leaning Outcomes

By the end of this presentation, you will be able to:

1. Understand the aims, objectives and scope of the Medical Device Regulation and the In Vitro Diagnostic Medical Device Regulation
2. Know the roles that the EC, Competent Authorities, Manufacturers and Notified Bodies play in the delivery and compliance with the regulations
3. Understand the role of standards and how Medical Devices are classified
4. Understand the importance of Clinical Evaluation
5. Understand the role of EUDAMED in promoting patient safety through the use of identification systems for medical devices

To Join the Webinar

Please register for the event by filling out the Webinar Registration Form. The instructions will be shown on the screen when you submit the form, for you to keep a record of them.

Continuing Education:

A certificate of attendance will be issued after the webinar. The session will be an hour of Continuing Education.