MEDTECH & PHARMA
PLATFORM

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Virtual Training Course

Introduction to clinical Evaluation under the MDR

26 May 2021 | 1:00 pm - 3:45 pm CEST

Objectives

This training will provide a comprehensive overview of the requirements related to the clinical evaluation of medical devices under the Regulation (EU) 2017/745 on medical devices (MDR). The course will present complementary perspectives on medical devices from industry and Notified Body experts.

Agenda

- Introduction to the MDR and to the requirements for clinical evaluation under the MDR
- Practical considerations for the preparation of the clinical evaluation report
- Data considerations for clinical review of drug/device combination products
- Pitfalls of the clinical evaluation under the MDR from a Notified Body perspective

Registration fee

Standard rate: CHF 400.-*
Member rare (Members of SwAPP, MPP, RDAF): CHF 350.-*
*Fees subject to VAT.

SwAPP credits

Training courses organized by the Medtech & Pharma Platform (MPP) are accredited by the Swiss Association of Pharmaceutical Professionals (SwAPP). Participants in this training will receive 3 SwAPP credits.

Register now

Course Leaders

Shayesteh Fürst-Ladani
SFL CEO / MPP President

Shayesteh is the CEO of the SFL Group of Companies and the President of the Medtech & Pharma Platform Association (MPP). She has extensive experience actively shaping healthcare policy and regulatory framework for drugs, medical devices and combined products. Before founding SFL, Shayesteh held senior positions as Head of Global Regulatory Affairs and Head of Regulatory Affairs for Development Products at biotech and major pharmaceutical companies.

Marta Swierczynska
Senior Manager Regulatory Affairs at SFL

At SFL, Marta leads projects focusing mainly on regulatory and medical aspects for medical devices, IVDs, and combination products. She advises clients on regulatory strategies for a broad range of products across different therapeutic areas and prepares regulatory documents required for submission to Notified Bodies and Health Authorities. She prepared MDR-compliant clinical evaluation reports for various Class I, Class II a/b, and Class III medical devices.

Patricia McHugh Giordano
Executive Director, Medical Safety Lead for Devices and Product Quality at MSD

Patricia established Clinical Safety and Risk Management for Devices and Product Quality at MSD, providing end-to-end cross-enterprise product safety and medical device life-cycle risk management support. Before that she worked at Johnson & Johnson, where during a 14-year span she worked as a physician in all three sectors of the company: Pharmaceuticals, Consumer Products and Medical Devices. Dr. Giordano earned a B.S. in Chemical Engineering from Drexel University as well as a degree in Osteopathic Medicine and Board Certification in Family Medicine at the Philadelphia College of Osteopathic Medicine.

Joshua Samuels
Director of Clinical Evaluations at Johnson & Johnson

Joshua Samuels is the Director of Clinical Evaluations at Johnson & Johnson, overseeing the Ethicon and Ethicon Endo Surgery/Digital Robotics businesses. He has overseen the writing, reviews, approval, Notified Body reviews, and/or audits of >200 unique CERs, including Class I, IIa, IIb, and III devices for both MDD and MDR. Joshua has also overseen over a dozen SSCP submissions to notified bodies. Joshua has his PhD in Biomedical Engineering from Drexel University with a focus on the development of diagnostic and therapeutic medical devices related to chronic wound healing.

Alice Genevet
Senior Manager Medical Affairs & Regulatory Affairs at SFL

Alice leads medical communication and regulatory projects, providing support to SFL clients for the development, filing, and maintenance of healthcare products, as well as for effectively negotiating and liaising with responsible authorities. Alice is involved in the preparation, review and submission of high-quality regulatory documentation for EMA, Swissmedic, and FDA for medicinal products as well as for medical devices. The documents and materials she develops include scientific advice briefing booklets, orphan designation dossiers, pediatric investigation plans, and clinical evaluation reports.

Ulrich Nitsche
Clinical Reviewer at TÜV-SÜD

Dr. Nitsche works as a Clinical Reviewer in the Clinical Center of Excellence at the Notified Body TÜV SÜD (CE 0123). He is responsible for the assessment of the clinical evaluation of high-risk devices under MDR. In addition, he is subject matter expert for the clinical oversight of the sampling plan for class IIa/IIb devices. He is a medical doctor and board-certified abdominal surgeon. In addition to his MD, he holds a Ph.D. degree in Medical Life Science and Technology and has longtime experience in basic medical science as well as in preclinical and clinical investigations. He has a postdoctoral lecture qualification for surgery and is an active emergency physician.

About Medtech & Pharma Platform (MPP) Association

MPP is a cross-sectoral not-for-profit industry Association focusing on combined products. MPP is made up of Medtech, Pharma and Tech companies dedicated to enhancing synergies between the sectors and to providing a cross-sectoral forum to exchange knowledge, collaborate in technology and regulatory areas as well as to promote product development and innovation. The Association aims to further strengthen advocacy work for companies to reduce time to market for drugs, devices and combinations thereof, improve access to innovative products and better match patients' needs.

Benefit from the input of recognized leaders in an interactive and accessible format
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