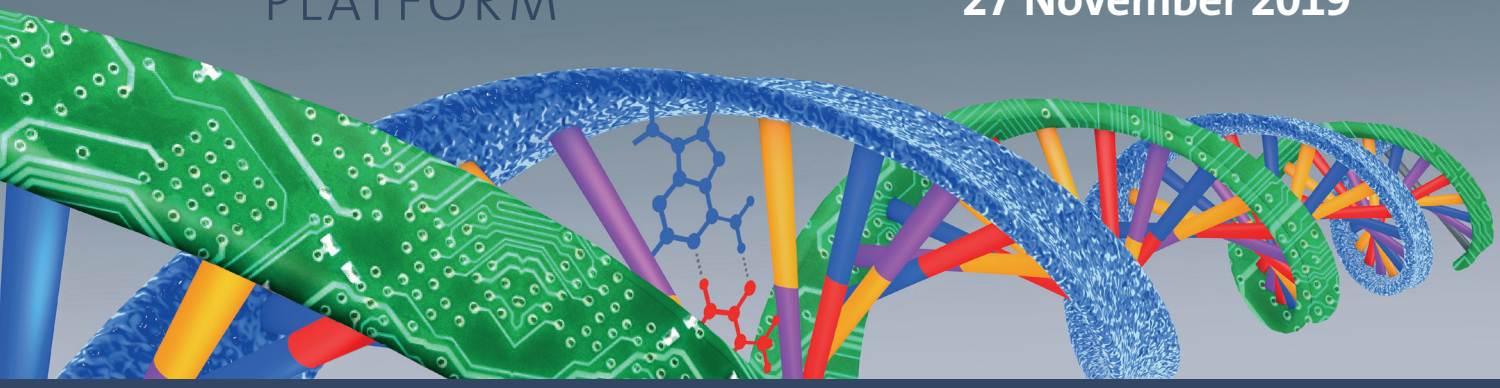
MEDTECH & PHARMA PLATFORM

1-Day Training Course
27 November 2019



Overview of key requirements for combination and substance based products under MDR

27 November 2019
9:00 am - 5:00 pm
Basel, Switzerland

Information and registration:
www.medtech-pharma.com

Objectives

To provide a comprehensive overview of the regulatory system and requirements for medical devices in Europe under the Medical Devices Regulation (MDR) including an update on the most recent developments and implementation timelines.

The Combination product area continues to show great growth and remains an important area in the medical sector, additionally Article 117 of the MDR amends the Medicinal Product Directive and outlines new requirements for the Pharmaceutical Industry and Integral drug-device combinations

The aim of the course is to provide a comprehensive overview of the regulatory system and requirements for medical devices in Europe with particular focus on combination and substance based products, the training shall also provide an update on the most recent developments and implementation timelines for the MDR.

Case studies and practical examples will complement the training.

Course leaders

- Theresa Jeary, Head of Combination Products at SFL
- Stephan Affolter, Head of Quality System & Regulatory Affairs at Ypsomed
- Karin Schulze, Head of Medical Devices at SFL

About Medtech & Pharma Platform (MPP) Association

The MPP enhances the synergies between medtech and pharmaceutical industries by establishing a forum to exchange knowledge and collaborate in technology and regulatory areas.

Agenda

Introduction to the MDR

- Highlight of the key changes for the MDR 2017/745
- Timelines, transitional provisions and NB designation update

Special focus session: Combination Products under MDR

- Article 117 – Implications and requirements for Medicinal products incorporating an integral medical device, Timescales and Notified Body Expectations
- Co-packaged and Cross-Labelling of Devices with Medicinal Products
- Devices with ancillary medicinal product / Human blood derivative – Changes to Rule 14 and the Conformity Assessment requirements under MDR
- Rule 21 - Substance based devices – Classification considerations, Impacts for Manufacturers, data requirements and assessment routes under the MDR

Registration fee

Standard rate: 500 CHF*
Member rate: 400 CHF*
*Fees subject to VAT.

Register now

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