



[www.medtech-pharma.com](http://www.medtech-pharma.com)

## Virtual Training Course

### Introduction to the EU MDR art. 117 and single integral drug/device combination products

16 February 2021 | 2:00 pm - 5:00 pm (CET)

#### Objectives

This training provides a comprehensive overview of the requirements and latest updates related to Notified Body Opinions for single integral drug/device combination products under art. 117 of the Regulation (EU) 2017/745 on medical devices (MDR).

After the end of the implementation period for the MDR on 26 May 2021, applicants will have to submit an opinion issued by a Notified Body to obtain a marketing authorization for medicinal products forming a single integral drug/device combination product with a medical device. This course will present complementary perspectives from the pharmaceutical industry, device manufacturer and Notified Body on key aspects of the applicable provisions.

#### Agenda

- Introduction to art. 117 MDR and overview of the challenges for single integral drug/device combination products
- Perspective of a Notified Body on art. 117 MDR
- Lessons learnt from the first Notified Body Opinions from the industry perspective

#### Registration fee

Standard rate: CHF 350.-\*

Member rate (Members of SwAPP, MPP, RDAF, SBA, Swiss Medtech): CHF 300.-\*

\*Fees subject to 7.7% VAT.

#### Course leaders

- Shayesteh Fürst-Ladani, SFL CEO and MPP President
- Christiana Hofmann, Team lead Non Active Medical Devices / Article 117 MDR at TÜV-SÜD
- Stephan Affolter, Regulatory and Quality Intelligence Manager at Ypsomed
- Mike Wallenstein, Global Head MDR Implementation and DD&C Compliance at Novartis

#### About MPP Association

The Medtech & Pharma Platform (MPP) is a cross-sectoral not-for-profit industry association focusing on combined products. MPP is made up of Medtech, Pharma and Software companies dedicated to enhancing synergies between the sectors and to provide 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.

[Register now](#)