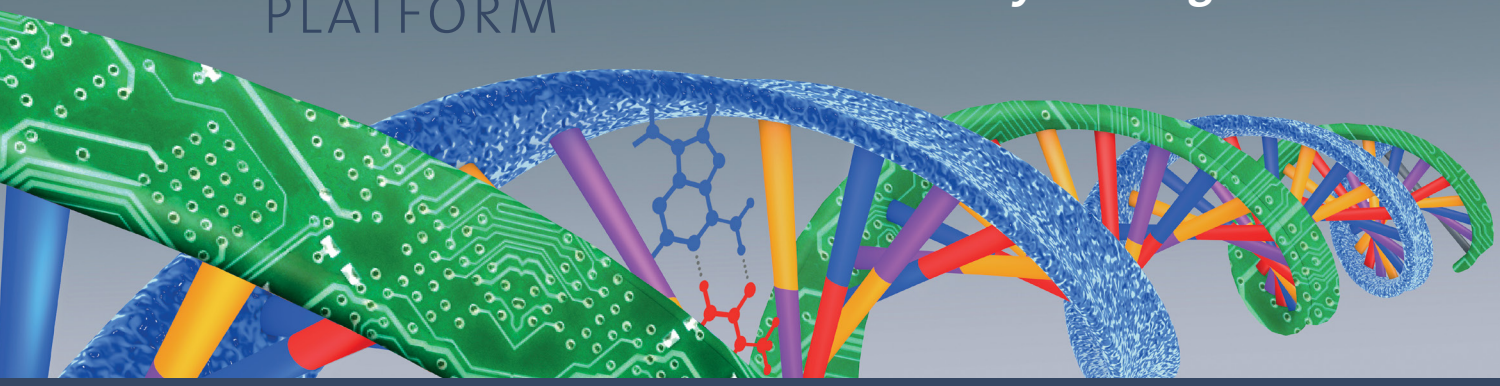
MEDTECH & PHARMA
PLATFORM

1-Day Training Course



# Overview of Medical Devices Regulation and Impact on Industry

February 26, 2018
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 new Medical Devices Regulation (MDR) .

Training in the application of regulatory rules by means of **case studies** and **practical examples**.

## Course leaders

- Karin Schulze, Head of Medical Devices at SFL
- Shayesteh Fürst-Ladani, President of the MPP

## Registration fee

Standard rate: 600 CHF*

*Fees subject to VAT.

## About Medtech & Pharma Platform Association

The Medtech & Pharma Platform (MPP) focuses on the synergies between medtech and pharmaceutical industries by establishing a forum to exchange knowledge and collaborate in technology and regulatory areas, as well as to promote product development and innovation.

## Agenda

- Introduction to the MDR
- New medical devices scopes according to Implementing Regulation 2017/2185
- New stakeholders such as MDCG
- Notified body selection considerations in the changing regulatory framework
- New classification rules
- Combination products in the EU - regulatory routes to the market
- New CE certification process, including scrutiny mechanism for high risk devices
- Technical documentation
- Clinical investigation and clinical evaluation, sources, and equivalence
- Post-market clinical follow-up and surveillance requirements
- New reports requested by MDR
- Transparency requirements
- Timelines and transitional provisions

## Point of contact

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