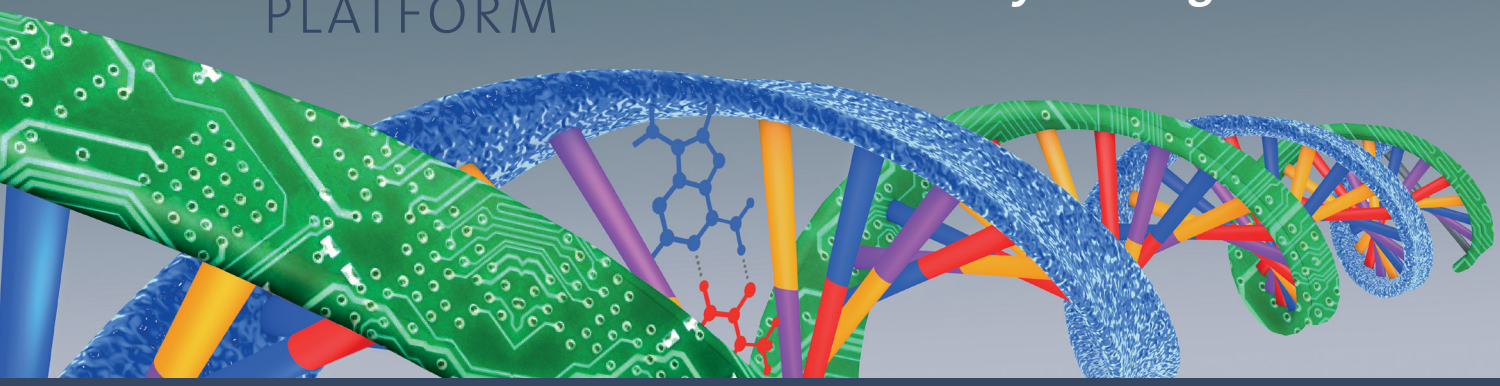
MEDTECH & PHARMA
PLATFORM

1-Day Training Course



Overview of Medical Devices Regulation and Workshop on Clinical Evaluation

March 28, 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 new Medical Devices Regulation (MDR).

Training in the application of regulatory rules by means of a **workshop** and **practical examples**.

Course leaders

- Karin Schulze, Head of Medical Devices at SFL
- Julien Gaudias, Senior Manager Regulatory Affairs at SFL

Registration fee

Standard rate: 700 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
- New classification rules
- New CE certification process, including scrutiny mechanism for high risk devices
- Clinical investigation and clinical evaluation
- Post-market clinical follow-up and surveillance requirements
- New reports requested by MDR
- Timelines and transitional provisions
- Workshop on clinical evaluation under MDR / MEDDEV 2.7/1 rev.4

Point of contact

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Register

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