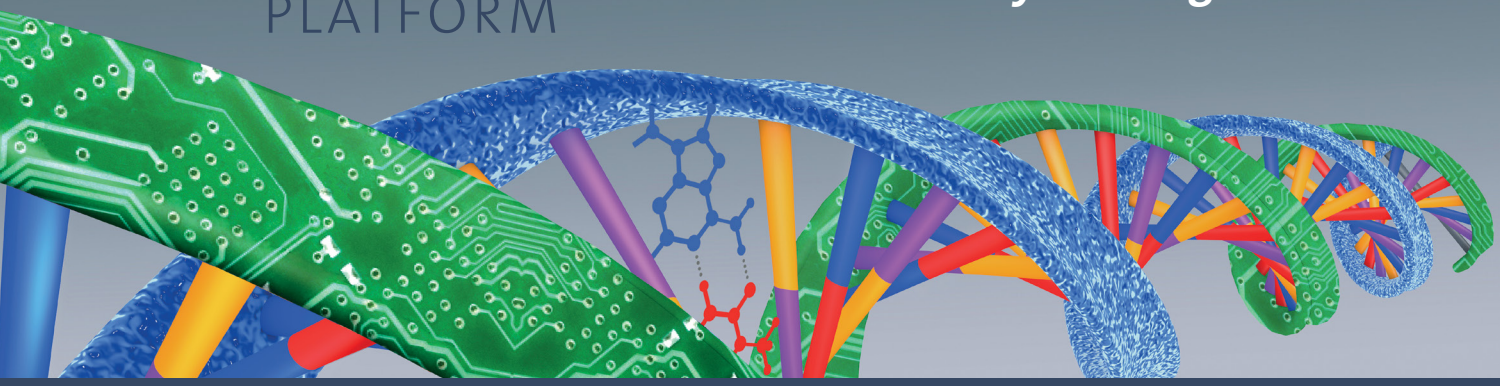
MEDTECH & PHARMA
PLATFORM

1-Day Training Course



Overview of Medical Devices Regulation and Impact on Industry

Special Focus: Clinical Decision Support Software and Apps under the Regime of the MDR

June 17, 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 most recent developments and implementation timelines.

As software and apps become increasingly important in the medical sector, the training will provide legal and regulatory perspectives on questions related to software as medical devices.

Case studies and practical examples will complement the training.

Course leaders

- Dr. Karin Schulze, Head of Medical Devices at SFL
- Dr. Wolfgang A. Rehmann, Partner Life Sciences at Taylor Wessing Munich

Registration fee

Standard rate: 700 CHF*

*Fees subject to VAT.

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
  - 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

- Special focus: Clinical Decision Support Software and Apps under the regime of the MDR
  - Software as medical device
  - Classification of software according to the MDR
  - Definition of medical purpose
  - Labelling Apps
  - Software as an accessory
  - Liability issues with regard to software under the MDR

Point of contact

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Register

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