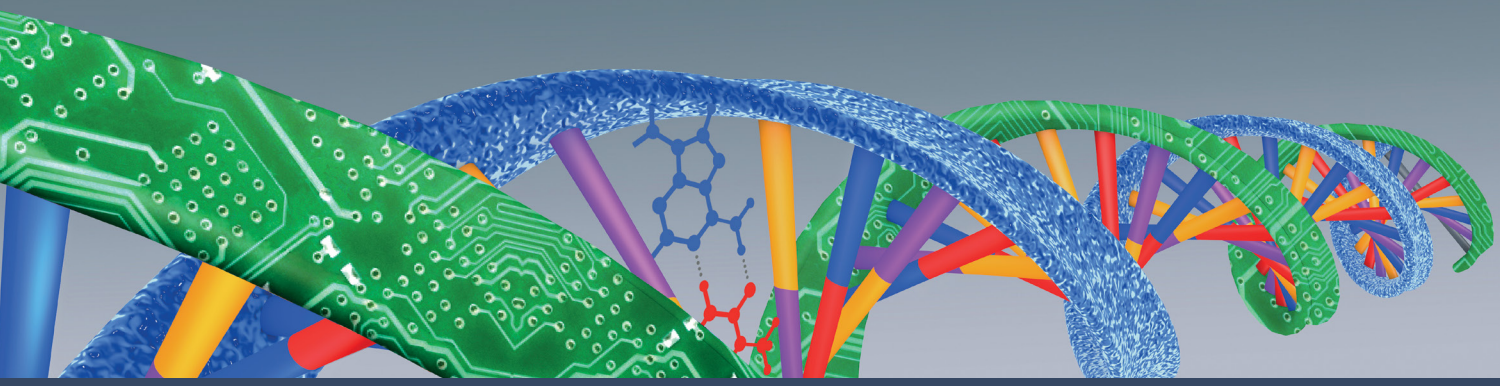
MEDTECH & PHARMA
PLATFORM

1-Day Training Course
17 June 2019 | Basel



Overview of Medical Devices Regulation and Impact on Industry

Special Focus: 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 regulatory perspectives and hands on experience on questions related to software as medical device.

Case studies and practical examples will complement the training.

Course leader

- Karin Schulze, Head of Medical Devices, SFL
- Miguel Cárdenas, Regulatory Associate Director Medical Devices, Novartis
- Mithun Ratnakumar, Lead Expert Software Development, SaMD projects, Novartis
- Sonja Lederhilger, Lead Human Factors Engineering, Novartis

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

- Software and Apps under the regime of the MDR
  Regulatory aspects
  - Software as medical device
  - Classification of software according to the MDR
  - Definition of medical purpose
  - Labelling Apps

  Development aspects
  - Intended use and risk classification
  - Systems engineering and standards
  - Cybersecurity
  - Human Factors Engineering

  Connected Devices

Register now

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