

# Workshop – Live Event

## Basics of Regulatory Affairs in MedTech

EPFL room Auditorium SG1

**Tuesday**  
**31 August, 2021**  
**09.00 – 17.00**



**This training provides you with the basics of regulatory affairs in MedTech with the focus on MDR and IVDR (Medical Devices and In-Vitro Diagnostic Medical Devices Regulation). Get an overview of the regulatory landscape, hear about the basic concepts and principles and get insights into the necessary steps but also pitfalls when bringing a MedTech product to the market. Discuss with the experts.**

### Training Objective

- Get an overview of the regulatory landscape and regulatory stakeholders in MedTech
- Understand the major principles, concepts and processes
- Learn to sequence the necessary steps and build awareness of possible pitfalls when bringing a MedTech product to the market
- Know where and how to find required information

### Target Audience

- Researchers in the field of translational medicine
- Employees from spin-offs, start-ups and SMEs, who intend to bring a product to the market
- Employees from companies interested in getting an overview on regulatory affairs
- Investors in medical devices who would like to understand risks and opportunities regarding the evolving regulatory framework in EU

### Prerequisites

- Affinity to or involvement in MedTech or Life Sciences
- Basic understanding of good practices in product development and innovation
- Technical / scientific background or commercial background linked to Life Sciences products

### Subscription

<https://medidee.com/workshop-medidee-epfl/>

The number of participants is limited.

## **PROGRAM**

### **31<sup>st</sup> of August**

#### **09.00 Welcome**

Frédéric Reymond, Key Account Manager, Innovaud  
André Catana, EPFL Start-up Unit  
Niels Lion, Deputy director Center for Neuroprosthetics, EPFL

#### **09.20 – 10.30 Introduction – Steps to CE Mark for Medical Devices**

Dr. Jurjen Zoethout, Senior Associate, Medidee Services

- MDR / IVDR
- Medical device classification – conformity assessment
- General Safety and Performance Requirements (GSPR)
- State of the art concept – principle of presumption of conformity
- Role of Notified Bodies and working with Notified Bodies
- Status update – implementation of MDR / IVDR
- Adoption of EU legal framework in Switzerland

#### **10.30 – 10.45 Coffee break**

#### **10.45 – 12.00 V&V and Technical Documentation**

Dr. Linda Ahnen, Senior Associate, Medidee Services

- Setting up a design & development process
- From user requirements to design validation
- Design verification and pre-clinical validation
- Technical documentation as evidence for compliance

#### **12.00 – 13.00 Lunch break**

#### **13.00 – 13.45 Clinical Evidence**

Dr. Linda Ahnen, Senior Associate, Medidee Services

- Clinical data, clinical evaluation and equivalence discussion
- Post market surveillance & post market clinical follow-up

#### **13.45 – 14.45 US Market Access for Medical Devices**

Dr. William Enns-Bray, Senior Associate, Medidee Services

- Regulatory framework
- Classification: 510(k), De Novo, HDE, PMA
- FDA medical devices databases
- Pre-submission, Breakthrough and STeP programs
- Differences between US and EU regulatory frameworks

#### **14.45 – 15.00 Coffee break**

#### **15.00 – 16.00 Digital Health**

Dr. William Enns-Bray, Senior Associate, Medidee Services

- Medical device software qualification & classification in EU/US
- Cybersecurity, artificial intelligence, applicable standards & guidance

#### **16.00 – 16.30 Start-up and Regulatory – Avoiding Pitfalls**

Michael Maier, Senior Partner, Medidee Services  
– Milestones of a medical device innovation project, a different view

#### **16.30 – 16.45 Closing words**

Frédéric Reymond, Key Account Manager, Innovaud  
Niels Lion, Deputy director Center for Neuroprosthetics, EPFL

## **Organizers**

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