

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

31st of August 2021

09.00 Welcome

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

09.15 – 10.45 Introduction – Steps to CE Mark for Medical Devices

Dr. Jurjen Zoethout, Chief Operating Officer, 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

10.45 – 11.00 Coffee Break

11.00 – 12.00 V&V and Technical Documentation

Dr. Valentina Lintas, Project 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. Valentina Lintas, Project 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. Elena Lucano, Project 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. Elena Lucano, Project 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

Dr. Jurjen Zoethout, Chief Operating Officer, 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

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Startup Launchpad