Online Workshop

Basics of Regulatory Affairs in MedTech

Tuesday to Thursday
29 – 30 June and 1 July, 2021
10.00 – 12.00 CEST

Canton of Zurich
Department for Economic Affairs
Office for Economy and Labour

ETH zürich

life science zurich
business network

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

Registration via zh.ch/ra-medtech

- The workshop is free of charge.
- You will receive the login information for the webinar by email on June 28th 2021
- A certificate of attendance will be issued for participants that participated on all three days

PROGRAM

29th of June

10.00 **Welcome**

Danielle Spichiger, President Life Science Zurich Business Network, Director ClusterLife Sciences, Business and Economic Development (AWA), Canton of Zurich
Dr. Urs Zuber, Head Industry Relations, ETH Zurich

10.10 – 12.00 **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

30th of June

10.00 – 11.00 **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

11.00 – 12.00 **Digital Health**

Dr. William Enns-Bray, Senior Associate, Medidee Services
- Medical device software qualification & classification in EU/US
- Cybersecurity, artificial intelligence, applicable standards & guidance

1st of July

10.00 – 11.00 **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

11.00 – 12.00 **Clinical Evidence**

Dr. Linda Ahnen, Senior Associate, Medidee Services
- Clinical data, clinical evaluation and equivalence discussion
- Post market surveillance & post market clinical follow-up

Organizers

Business and Economic Development (AWA), Canton of Zurich
ETH Zurich Industry Relations
Life Science Zurich Business Network

Partner

Medidee Services AG

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