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

Partner
Medidee Services AG
With its headquarter in Lausanne and a branch office in Olten and offices in Germany, Denmark, Belgium and USA, Medidee is a global services provider serving companies of all sizes ranging from academic start-ups to majors. Services cover Scientific, Regulatory, Clinical and Quality System support along all steps of product development, from initial project idea to certification or regulatory clearance. Key services include regulatory / clinical strategy, development of CER, CIP, technical documentation, verification & validation support incl. statistics in V&V and clinical, development of scientific rationales for V&V e.g. biological risk assessments, Risk Management, Post Market Surveillance and PMCF, supporting Notified Body and Competent Authority contacts, supporting competent authority inspections e.g. FDA, quality system implementation and maintenance, MDSAP readiness. Medidee’s product expertise covers Active Implants, Medical Devices incl. substance based devices and IVD.
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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, startups 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

Register and get your ticket via Ticketino
The workshop is limited to 50 participants
CHF 100 incl. lunch

Programme

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

10.10 - 12.15 Introduction – Steps to CE Mark for Medical Devices
Michael Maier, Senior Partner, 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

12.15 – 13.15 Lunch and Networking

13.15 – 14.10 V&V and Technical Documentation
Dr. Linda Ahnen, Scientific Expert, 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

14.10 – 15.00 Clinical Evidence
Dr. William Enns-Bray, Scientific Expert, Medidee Services
- Clinical data, clinical evaluation and equivalence discussion
- Post market surveillance & post market clinical follow-up

15.00 – 15.20 Coffee Break

15.20 – 16.20 US Market Access for Medical Devices
Dr. Jurjen Zoethout, Site Manager, Medidee Services
- Regulatory framework
- Classification: 510(k), De Novo, HDE, PMA
- FDA medical devices databases
- Pre-submission programme
- Differences between US and EU regulatory frameworks

16.20 – 16.45 Start-up and Regulatory – Avoiding Pitfalls
Michael Maier, Senior Partner, Medidee Services
- Milestones of a medical device innovation project, a different view