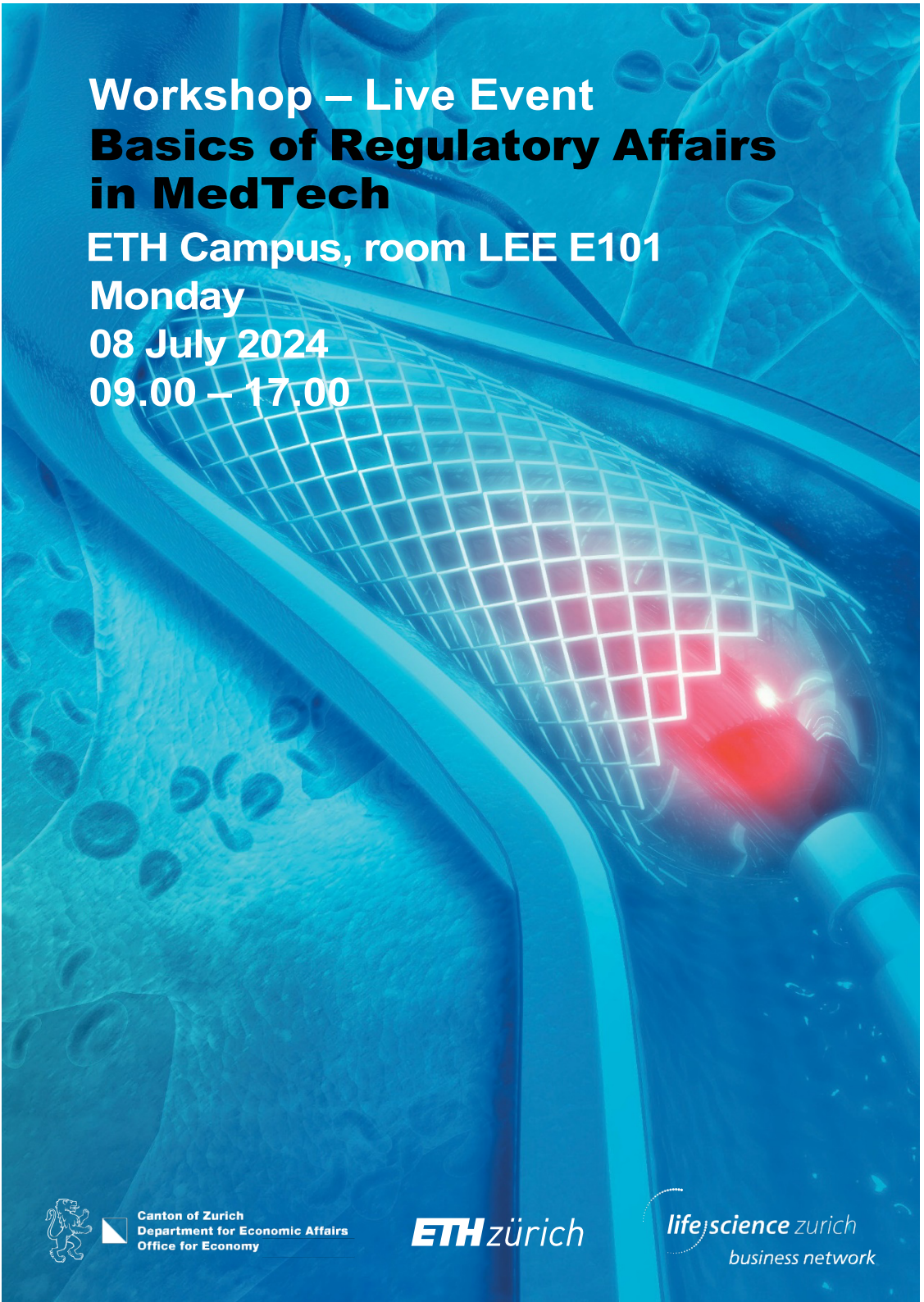

Workshop – Live Event
Basics of Regulatory Affairs in MedTech

ETH Campus, room LEE E101
Monday
08 July 2024
09.00 – 17.00

Canton of Zurich
Department for Economic Affairs
Office for Economy

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 DevicesRegulation). Get an overview of the regulatory lands- cape, 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. Discusswith 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
Register and get your ticket via Ticketino
https://www.ticketino.com/en/event/workshop---live-event-basics-of-regulatory-affairs-in-medtech/191036

The workshop is limited to 50 participants
CHF 100 incl. lunch and coffee break

Workshop location
ETH, LEE E 101 - Leonhardstrasse 21, 8092 Zürich

PROGRAM

08th of July 2024

9.00 Welcome
Danielle Spichiger, Head Life Sciences, Business & Economic Development, Canton of Zurich
Dr. Urs Zuber, Head Industry Relations, ETH Zurich
Ivo Schauwecker, Managing Director, dTIP, ETH Zurich

9.15 – 10.45 Introduction – Steps to CE Mark for Medical Devices
Dr. Linda Ahnen, Director, Regulatory & Clinical Affairs - Veranex
- 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 US Market Access for Medical Devices
Alba Gutierrez, Quality & Regulatory Affairs Manager - Veranex
- 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

12.00 – 13:00 Lunch break

13.00 – 14.00 V&V and Technical Documentation
Anna Amovilli, Quality & Regulatory Affairs Manager - Veranex
- Setting up a design & development process
- From user requirements to design validation
- Design verification and pre-clinical validation
- Technical documentation as evidence for compliance

14.00 – 14.45 Clinical Evidence
Dr. Linda Ahnen, Director, Regulatory & Clinical Affairs - Veranex
- Clinical data, clinical evaluation and equivalence discussion
- Post market surveillance & post market clinical follow-up

14.45 – 15:00 Coffee break

15.00 – 16.00 Quality Management System
Dietmar Schaffarczyk, Regulatory Expert - dTIP, ETH Zurich
- Importance and timing of QMS implementation
- Key ISO 13485 QMS requirements

16.00 – 16.45 Start-up and Regulatory – Avoiding Pitfalls
Dr. Jurjen Zoethout, VP Regulatory & Quality Affairs - Veranex
- Milestones of a medical device innovation project, a different view

16.45 – 17.00 Wrap Up & Closing Words

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

Partner
dTIP - ETH Zurich
dTIP is an ETH technology platform created to support researchers in clinical evidence generation and support entrepreneurs with the regulatory aspects of product development. dTIP is built around three interdisciplinary expert units, staffed with clinical trials, data management and regulatory experts. We collaborate with clinical and non-clinical partners in academia and/or industry to provide a high quality service for clinical trials and throughout the product development life cycle.

Veranex Switzerland SA
Veranex is a comprehensive, global, tech-enabled service provider dedicated to the medical technology industry. Within Quality, Regulatory and Clinical Affairs for medical devices, we provide support to medical device manufacturers, public organizations and health professionals focused on compliance with legal requirements associated to the design, development, manufacture, validation and commercialization of various types of medical devices, in-vitro diagnostic devices, standalone & embedded software. Our services cover all steps of the product development, from initial project idea, to clinical investigations and certification or regulatory clearance worldwide.

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