Online Workshop

Digital Health

The Regulatory Landscape

Tuesday to Thursday

01 – 03 February 2022

10.00 – 12.00 CET

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

ETH zürich

life science zurich
business network

Organizer

Business & 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, Philippines 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 Clinical Investigations Protocols, Clinical Evaluation Reports, 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 related to digital health. Get an overview of the regulatory landscape, hear about the basic concepts and principles, get insights into the necessary steps and anticipate typical pitfalls when bringing a digital health product to the market.

Discuss with the experts.

Training Objective

- Get an overview of the regulatory landscape and requirements surrounding digital health applications
- Understand the major principles, concepts and processes
- Learn to sequence the necessary steps and build awareness of possible pitfallswhen bringing a digital health product to the market
- Know where and how to find required information

Target Audience

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

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 http://zh.ch/ra-digitalhealth

- The **workshop** is **free of charge**
- You will receive the **login information for the webinar** by email **a few days prior to the workshop**
- A **certificate of attendance** will be issued for participants that participated on all three days and completed the quiz

PROGRAM

1st of February

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 – 12.00 General introduction to Digital Health

Kim Rochat, Senior Partner, Medidee Services

- Digital health regulatory context
- Guidance and standards to comply with related requirements
- Key requirements and importance of IEC 62304

2nd of February

10.00 – 12.00 Cybersecurity assessment of medical devices

Dr. Gustavo Hernandes, Project Associate, Medidee Services

- Link between cybersecurity and regulatory requirements
- Key steps to ensure compliance with cybersecurity requirements
- Risk domains to cover in a cybersecurity assessment

3rd of February

10.00 – 12.00 Artificial intelligence and machine learning

Dr. Stamatia Pagoulatou, Project Associate, Medidee Services

- Artificial intelligence (AI) and machine learning (ML) in medical devices
- Regulatory framework of AI/ML medical devices
- Validation framework and key expectations