Online Workshop

Clinical Investigations – Medical Devices

Tuesday to Thursday
20 – 22 September 2022
10.00 – 12.00 CEST

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

ETH zürich

life science zurich
business network

Organizer
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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This training provides you a basic overview on clinical investigations for medical devices.

Get an overview of the regulatory landscape, hear about the basic concepts and principles and get insights into the necessary steps and anticipate typical pitfalls when planning and conducting a clinical study.

Discuss with the experts.

Training Objective

- Get an overview of the regulatory context and requirements on clinical studies
- Understand the major principles, concepts and processes required by ISO 14155 and ICH-GCP
- Learn to sequence the necessary steps in planning, designing, and conducting a clinical investigation
- 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 conduct clinical investigations on medical devices
- Employees from companies interested in getting an overview on clinical investigations

Prerequisites

- Affinity to or involvement in MedTech or Life Sciences
- Basic understanding of medical device regulation and development
- Technical / scientific background or commercial background linked to Life Sciences products

Registration via this Link

- The workshop is free of charge
- You will receive the login information for the webinar by email

PROGRAM

20th of September

10.00 Welcome

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

10.10 Introduction dTIP, ETH Zurich

Dr. Angela Frotzler, Managing Director, dTIP

- Introduction digital trial intervention platform (dTIP)

10.15 – 12.00 General introduction clinical investigation

Linda Ahnen, Senior Consultant, Medidee Services

- Regulatory context
- GCP core principles as defined in ISO 14155:2020
- Planning and study design

21st of September

10.00 – 12.00 Statistics, stakeholders and essential documents

Anna Amovilli, Project Associate, Medidee Services

- Statistical concepts
- Roles and responsibilities of stakeholders
- Essential documents

22nd of September

10.00 – 12.00 Clinical investigation conduct and close out

Jérôme Randall, Project Associate, Medidee Services

- Submission and registration
- Monitoring
- Safety reporting
- Study close-out