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**UNIVERSITÄT
BERN**

GCP Refresher for clinical research 2021

GCP Lectures organized by CTU Bern

Contact

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GCP Refresher for clinical research 2021

Teaching language
English

Discussions
German or English

Course objectives

This course is aimed at providing a refresher training to clinical investigators with the essential knowledge of Good Clinical Practice (GCP) and of other regulatory and ethical requirements, and the skills for contributing to clinical trials.

Course content

The GCP Refresher course is split in four parts, whereas each part of the course is held as a separate CTU Lecture.

- Lecture 1** consists of the basic principles and study project required documentation.
- Lecture 2** addresses study preparation and conduct.
- Lecture 3** continues on study conduct and project closure.
- Lecture 4** is kept flexible and will address additional learning contents such as upcoming regulatory changes or key topics in clinical research.

Overall the following areas will be covered with all CTU Lectures:

- Research types
- Laws & regulations in Switzerland
- Roles & responsibilities within a study project
- Project feasibility, costs, funding, budget
- Quality management structures and key study document requirements
- Task assignment
- Submission & reporting requirements
- Risk minimization
- Handling and storage of study medication / medical devices
- Study surveillance via monitoring, audits
- Informed consent process

- Protocol adherence
- Safety reporting
- Study end process and respective reporting obligations
- Changes in the regulatory environment or other study relevant topics.

Target audience

The course is designed to approach those who have already gained experience in clinical trials and wish to refresh their knowledge of the conduct of such trials. Please note: this GCP course does not replace the Clinical Investigators Course I and II (Basic, Advanced), as it is a refresher of those course contents only. Open for study nurses, Principal Investigators.

Registration & course fee

Please register online at www.ctu.unibe.ch for each CTU Lecture individually. All lectures in 2021 are free of charge provided by CTU Bern.

Online registration for each lecture:
www.ctu.unibe.ch

Legal requirements

Swissethics has recognized that this training course fulfills the published requirements for GCP Refresher course program of Art. 10 HRA and Art.6 ClinO.

For additional information:
training@ctu.unibe.ch

Certificate

In order to obtain GCP Refresher course certification, you are required to participate in all four CTU Lectures covering the respective topics.

Certificate will be issued at the end of the course.