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**UNIVERSITÄT
BERN**

GCP Refresher for clinical research

Organized by CTU Bern

Contact

Universität Bern
CTU Bern
Mittelstrasse 43
3012 Bern
Phone. +41 31 684 34 04
training,ctu@unibe.ch
www.ctu.unibe.ch

GCP Refresher for clinical research

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

This half-day compact course consists of four parts of 30 to 45 minute presentations, followed by a question and answer session. The course can only be attended as a whole.

- Part 1** consists of the basic principles and study project required documentation.
- Part 2** addresses study preparation and conduct.
- Part 3** continues on study conduct and project closure.
- Part 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:

- 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.
CHF 120

Online registration:
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.

Certificate

In order to obtain the GCP Refresher course certificate, you are required to register individually with your full name and attend the entire course, i.e. attend all four parts in full length. The certificate will be issued at the end of the course.

For additional information:
training.ctu@unibe.ch