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**UNIVERSITÄT
BERN**

1 DAY COURSE
ORGANIZED BY CTU BERN

Clinical Investigators II: advanced GCP and clinical research training

Contact:
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Clinical Investigators II: advanced GCP & clinical research training

Course objectives

This course is aimed at providing investigators with advanced knowledge of Good Clinical Practice and of other regulatory and ethical requirements, and the knowledge and skills for developing study protocols, conducting clinical studies and publishing study reports.

Course content

Teaching language
English

This one-day course will consist of a series of interactive lectures supplemented with workshops.

Discussions
German or English

The topics covered will include:

- Developing a research question
- Basic statistical concepts
- The role of the hospital pharmacy in clinical trials
- Contracts
- Submission to competent authorities
- Quality Management System
- Feasibility & costs

Target audience

This course is relevant to those who are keen to gain more understanding of the design and conduct of clinical trials.

Attendance would be primarily appropriate for:

- Sponsor-Investigators (mandatory) and Principal Investigators initiating or directing clinical trials (as required by ethics committees and regulatory authorities)

Others such as members of ethics committees, study nurses, biostatisticians and trial coordinators interested in clinical research are also welcome.

Registration & course fees

Please register online at www.ctu.unibe.ch

Online registration:
www.ctu.unibe.ch

CHF 300 internal participants (staff of Bern University Hospital and University of Bern)

CHF 500 external participants

Legal requirements

Swissethics has recognized that this training course fulfills the published requirements for Sponsor-Investigator Level courses. Participants finishing this training program fulfil the requirements of Art. 10 HRA and Art.6 ClinO.

Certificate & credit points

Certificate will be issued at the end of the course.

For additional information:
training@ctu.unibe.ch

The attendance is acknowledged with

- 8 credits of the SIWF/ISFM, Schweizerisches Institut für ärztliche Weiter- und Fortbildung, «SIWF-approved»
- 8 credits of the SGKPT, Schweizerische Gesellschaft für Klinische Pharmakologie und Toxikologie
- 6.5 credits of the SGPM, Schweizerische Gesellschaft für Pharmazeutische Medizin

In addition 0.5 European Credits Transfer System (ECTS) credit will be granted to participants successfully completing a written examination at the end of the training course.