

Good Clinical Practice (GCP) Refresher Course

Venue: Swiss TPH, Kreuzstrasse 2, 4123 Allschwil, Switzerland

PROGRAMME

13:00 – 16:45 h

Registration

12:40 Registration Opens

General | Welcome

13:00 Introduction of teachers, course program and conditions

Lecture | Refreshing GCP Principles

13:15 Types of studies, Legal clinical trial framework in Switzerland, Regulations for clinical research - GCP, Study oversight

14:00 Bio-Break

Lecture | Refreshing GCP Principles (continuation)

14:05 Operational aspects

15:00 Break

Quiz

15:15 Questions on Good Clinical Practice guideline, study conduct and audit / inspection findings

16:45 End of Day

Mandatory Pre-reading (2 – 3 hours)

- Knowledge of Helsinki Declaration is expected
- ICH guideline E8 (R1) on general considerations for clinical studies
- Detailed reading of Guideline for good clinical practice E6(R2) – chapter 2, Principles
- Reading as needed of Guideline for good clinical practice E6(R2)

Assessment

- Online open book MC test after course
(20 questions - at least 70 % correct answers to pass and receive certificate)