

# Good Clinical Practice (GCP) Refresher Course

Venue: Allschwil, Swiss TPH - Belo Horizonte

## PROGRAMME

### 13:00 – 16:45 h

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#### Registration

12:40 Registration Opens

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#### General | Welcome

13:00 Introduction of teachers, course program and conditions

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#### Lecture | Refreshing GCP Principles

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

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14:00 Bio-Break

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#### Lecture | Refreshing GCP Principles (continuation)

14:05 Operational aspects

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15:00 Coffee Break

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#### Quiz

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

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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)