# Agenda GCP Refresher Course

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

## Work before the course

- knowledge of the “Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects” (Version October 2024, Helsinki) is expected
- read the ICH Guideline General Considerations for Clinical Studies - E8(R1)
- detailed reading of the “ICH Harmonised Guideline for Good Clinical Practice E6(R3)” - Principles
- read as needed the “ICH Harmonised Guideline for Good Clinical Practice E6(R3)”

(overall, approximately 2 – 3 hours).

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| 12:40h | Registration Opens |
| 13:00h | Introduction of teachers, course program and conditions |
| 13:15h | **Refreshing GCP Principles**<br>Types of studies, legal clinical trial framework in Switzerland, regulations for clinical research – GCP, study oversight |
| 14:00h | Bio-Break |
| 14:05h | **Refreshing GCP Principles (continuation)**<br>Operational aspects |
| 15:00h | Break |
| 15:15h | **Quiz**<br>Questions on Good Clinical Practice guideline, study conduct and audit / inspection findings |
| 16:15h | Individual multiple-choice test |
| 16:45h | **End of course** |

## Information:

**After the course, participants will need to pass a multiple-choice test with a minimum passing score of 70%.** A 'Certificate of Attendance" will be provided if the following conditions are met:

if the course was fully attended

if the individual multiple choice test was passed with at least 70 % correct answers