Swiss TPH, GCP Training

Good Clinical Practice (GCP) Training for Investigators and Study Teams

Venue: Allschwil, Swiss TPH - Belo Horizonte

Swiss TPH
Swiss Tropical and Public Health Institute
Schweizerisches Tropen- und Public Health-Institut
Institut Tropical et de Santé Publique Suisse
Associated Institute of the University of Basel

PROGRAMME

Day 1:

Registration Day 1

08:15 **Registration Opens**

General | Welcome

08:45 **Introduction of participants, course program and structure**

Lecture 1 | Introduction to Good Clinical Practice

09:00 **Motivation to conduct research with humans, Principles of Research Ethics, Introduction to ICH E6(R2) GCP Guideline**

10:10 **Coffee Break**

Lecture 1 | Introduction to Good Clinical Practice (continuation)

10:20 **Investigators responsibilities (details), Sponsor responsibilities (brief overview)**

Lecture 2 | Basic Statistical Concepts and Study Design

11:00 **Study designs, Research question, Avoidance of bias, Hypothesis testing & sample size, Introduction to risk assessment and management**

12:00 **Lunch Break**

Exercise 1 | Protocol Optimization

13:00 **How would you improve the example protocols?**

Lecture 3 | Source Records and Data Management

13:45 **From case report forms to final analysis**

14:45 **Coffee Break**

Exercise 2 | Critical review of Source Documents and CRF Design

15:00 **Principles of ALCOAC, Improving data quality from the Start**

Lecture 4 | Essential Documents and Archiving

16:00 **Essential documents, Trial Master File, Retention**

17:00 End of Day 1

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Day 2:

Lecture 5 | Focus on Informed Consent and Safety Reporting

09:00 **Key information and Investigator responsibilities**

10:15 Coffee Break

Exercise 3| Critical Review of an Informed Consent Form & Safety Quiz

10:30 **Analyse and discuss potential problems and ethical issues with the example informed consents**
Assessment of Adverse Events

Lecture 6 | Quality Management

11:30 **SOPs, Training, Monitoring, Auditing, Common audit and inspection findings**

12:30 Lunch Break

Lecture 7 | Research Misconduct and Fraud

13:30 **Definition and consequences, Case study**

Lecture 8 | Legal Background, Ethics Committees & Submission processes

14:15 **Introduction to HFG, Ethics landscape Switzerland, Swissmedic, BASEC**

Summary |

15:30 **13 Key Principles of ICH GCP; Key points of addendum E6 (R2), outlook to E6 (R3)**

16:00 End of Day 2 / End of Course

Information:

Additional time required: Prior to the course, participants will be expected to have read the **"Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects"** (*Version October 2013, Fortaleza*) and reviewed the "**ICH Harmonised Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)**" and the **ICH Guideline General Considerations for Clinical Studies E8(R1)** (approximately 3-4 hours).

After the course, participants will need to pass a competency assessment (multiple choice consisting of 20 questions) **with a minimum passing score of 70%.** A 'Certificate of Attendance" will be provided if the following conditions are met:

if both entire course days were attended
if the online test was passed with at least 70 % correct answers