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

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 **Historical Background, Research Ethics, Drug Regulations, Introduction to ICH E6 (R2) GCP Guideline, Investigators responsibilities**

10:15 **Coffee Break**

Lecture 1 | Introduction to Good Clinical Practice (continuation)

10:30 **Historical Background, Research Ethics, Drug Regulations, Introduction to ICH E6 (R2) GCP Guideline, Investigators responsibilities**

Lecture 2 | Basic Statistical Concepts and Study Design

11:00 **Defining the research question**

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 | Study 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 **Investigator Responsibilities**

10:15 Coffee Break

Exercise 3| Critical Review of an Informed Consent Form

10:30 **Analyze and discuss potential problems and ethical issues with the example informed consents**

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 Examples**

Lecture 8 | Legal Background, Ethics Committees & Submission processes

13:45 **Introduction to HFG, ethics landscape Switzerland, BASEC, Swissmedic**

Summary |

15:00 **13 Key Principles of ICH GCP;**
A look at addendum to ICH E6 (R2)

16:00 End of Day 2 / End of Course

Information:

Additional time: Prior to the course, participants will be expected to have read the "**ICH Harmonised Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)**" and the **"Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects"** (*Version October 2013, Fortaleza*) (appr. 3 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%.** Following successful completion, a Certificate of Training will be provided.