



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

**Location:** virtual via ZOOM

**Date/Time:** Day 1: 25 August 2020, 08:45 – 17:00  
Day 2: 26 August 2020, 09:00 – 16:00

**Language:** English

### Day 1

Module	Time	Agenda Item
Introduction	08:45 – 09:00	<b>Welcome</b> Introduction of participants, course program and structure
Lecture 1	09:00 – 10:15	<b>Introduction to Good Clinical Practice</b> Historical Background, Research Ethics, Drug Regulations, Introduction to ICH E6 (R2) GCP Guideline, Investigators responsibilities
	10:15 – 10:30	<b>Coffee break</b>
Lecture 1 (cont.)	10:30 – 11:00	<b>Introduction to Good Clinical Practice</b> Historical Background, Research Ethics, Drug Regulations, Introduction to ICH E6 (R2) GCP Guideline, Investigators responsibilities
Lecture 2	11:00 – 12:00	<b>Basic Statistical Concepts and Study Design</b> Defining the research question
	12:00 – 13:00	<b>Lunch break</b>
Exercise 1	13:00 – 13:45	<b>Protocol Optimization</b> How would you improve the example protocols?
Lecture 3	13:45 – 14:45	<b>Source Records and Data Management</b> From Case Report Forms to Final Analysis
	14:45 – 15:00	<b>Coffee break</b>
Exercise 2	15:00 – 16:00	<b>Critical review of Source Documents and CRF Design</b> Principles of ALCOAC; Improving Data Quality from the Start
Lecture 4	16:00 – 17:00	<b>Study Documents and Archiving</b> Essential Documents, Trial Master File, Retention



**Day 2**

Module	Time	Agenda Item
Lecture 5	09:00 – 10:15	<b>Focus on Informed Consent and Safety Reporting</b> Investigator Responsibilities
	10:15 – 10:30	<b>Coffee break</b>
Exercise 3	10:30 – 11:30	<b>Critical Review of an Informed Consent Form</b> Analyze and discuss potential problems and ethical issues with the example informed consents
Lecture 6	11:30 – 12:30	<b>Quality Management</b> SOPs, Training, Monitoring, Auditing; Common Audit and Inspection Findings
	12:30 – 13:30	<b>Lunch break</b>
Lecture 7	13:30 – 14:15	<b>Research Misconduct and Fraud</b> Definition and Consequences; Case Examples
Lecture 8	14:15 – 15:30	<b>Legal Background, Ethics Committees &amp; Submission processes</b> Introduction to HFG, ethics landscape Switzerland, BASEC, Swissmedic
Summary	15:30 – 16:00	<b>Summary</b> 13 Key Principles of ICH GCP; A look at addendum to ICH E6 (R2)

**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.