

AGENDA

Swissmedic Symposium Clinical Trials (*Train the Trainer*)

Tuesday, 4 November 2025, 09:00 – 16:30, Welle7, in Bern (Schanzenstrasse 5, 3008 Bern)

TIME	TOPIC	SPEAKERS
08:30 – 09:00	Registration & Welcome Coffee	
09:00 – 09:15	Opening and Introduction	Dr Simone Ferbitz Head of Division Clinical Trials
09:15 – 09:30	General Aspects to Consider for FIH/Early Phase I Clinical Trials with Medicinal Products	Isabelle Meienberger GCP/GVP Inspector
09:30 – 09:55	Expectations on Computerised Systems	Dr Reto Iannaccone GCP/GVP Inspector
09:55 – 10:15	Frequent Inspection Findings	Dr Mario Baresic GCP/GVP Inspector
10:15–10:45	Coffee Break & Networking	
10:45 – 11:15	1 Year ClinO Revision	Dr Catherine Berset Kipouros Clinical Study Assessor
11:15 – 11:45	Key Take Aways for Clinical Trial Submissions	Dr Carmen Campanile Patricia Plattner Clinical Study Assessors
11:45 – 12:00	Questions & Answers	Team Division Clinical Trials
12:00 - 13:15	Lunch Break & Networking	
13:15 – 14:45	Workshop 1: Staying Connected, Staying Compliant – ICH GCP Requirements Related to the Use of Electronic Devices	Dr Ruth Hinrichs Denis Mosimann GCP/GVP Inspectors
13:15 – 14:45	Workshop 2: From Findings to Fixes: Swissmedic Perspective on CAPA Plans	Dr Cyrile-Anne Curat Ingrid Löhr Kottmann GCP/GVP Inspectors
13:15 – 14:45	Workshop 3: Decentralised Clinical Trials	Dr Simona Berardi Vilei Head GCP/GVP Inspectorate Dr Nicole Torti GCP/GVP Inspector Silvia Stüdeli Clinical Study Assessor
13:15 – 14:45	Workshop 4: Quality & GMP – Special Aspects	Dr Verena Gafner Dr Guy Lemaillet Clinical Study Assessors
14:45 – 15:00	Change of Workshop Rooms	

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