

## AGENDA

### Swissmedic Symposium Clinical Trials (*Train the Trainer*)

Monday, 4 November 2024, Welle7, in Bern (Schanzenstrasse 5, Bern)

08:45 – 16:45

<b>TIME</b>	<b>TOPIC</b>	<b>SPEAKERS</b>
08:45 – 09:15	<i>Registration &amp; Welcome Coffee</i>	
09:15 – 09:30	<b>Opening and Introduction</b>	<b>Dr Simone Ferbitz</b> Head of Division Clinical Trials
09:30 – 10:00	Revision of the Clinical Trials Ordinance and its implication for clinical trial submissions	<b>Dr Verena Gafner</b> Senior Clinical Study Assessor
10:00 – 11:00	Major changes ICH GCP E6 R3 Ongoing safety evaluation	<b>Dr Reto Iannaccone</b> GCP/GVP Inspector <b>Dr Mario Baresic</b> GCP/GVP Inspector
11:00 – 11:30	<i>Coffee Break &amp; Networking</i>	
11:30 – 11:45	Fee reduction for non-commercially funded clinical trials	<b>Dr Simone Ferbitz</b> Head of Division Clinical Trials
11:45 – 12:15	Source data handling and location	<b>Dr Cyrille-Anne Curat</b> GCP/GVP Inspector
12:15 – 12:30	Customs Project	<b>Dr Mario Baresic</b> GCP/GVP Inspector
12:30 – 13:30	<i>Lunch Break &amp; Networking</i>	
13:30 – 15:00	<b>Workshop 1:</b> Sponsor oversight	GCP/GVP Inspectors: <b>Ingrid Löhr Kottmann</b> <b>Adisa Cokoja</b> <b>Denis Mosimann</b>
13:30 – 15:00	<b>Workshop 2:</b> Inspection findings	GCP/GVP Inspectors: <b>Isabelle Meienberger</b> <b>Dr Simona Berardi Vilei</b> <b>Dr Ruth Hinrichs</b>
13:30 – 15:00	<b>Workshop 3:</b> Revision of the Clinical Trials Ordinance and its implication for clinical trial submissions	Clinical Study Assessors: <b>Dr Catherine Berset Kipouros</b> <b>Dr Verena Gafner</b> <b>PD Dr Rolf Kaiser</b> <b>Silvia Stüdeli</b>
13:30 – 15:00	<b>Workshop 4:</b> Frequent Deficiencies in CTA/Amendment Submissions	Clinical Study Assessors: <b>Dr Mayra Latorre Martinez</b> <b>Dr Guy Lemaillet</b> <b>Dr Carmen Campanile</b> <b>Patricia Plattner</b> <b>Dr Caroline Lämmli</b> <b>PD Dr Thomas Schochat</b>

15:00 – 15:15	<i>Change of workshop rooms</i>	
15:15 – 16:45	<b>Workshop 1:</b> Sponsor oversight	GCP/GVP Inspectors: <b>Ingrid Löhr Kottmann</b> <b>Adisa Cokoja</b> <b>Denis Mosimann</b>
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15:15 – 16:45	<b>Workshop 4:</b> Frequent Deficiencies in CTA/Amendment Submissions	Clinical Study Assessors: <b>Dr Mayra Latorre Martinez</b> <b>Dr Guy Lemaillet</b> <b>Patricia Plattner</b> <b>Dr Carmen Campanile</b> <b>Dr Caroline Lämmli</b> <b>PD Dr Thomas Schochat</b>