

## Programme

# Swissmedic Symposium Clinical Trials (“Train the Trainer”)

Tuesday, 4 June 2019,

8:45 – 16:45, Swissmedic, Hallerstrasse 7, Berne, Room H044

Location/map: <https://www.swissmedic.ch> → About us → Contact

<b>Time</b>	<b>Themes</b>	<b>Speaker (Swissmedic)</b>
08:45 – 09:15	<i>Registration and Coffee</i>	
09:15 – 9:20	<b>Opening and introduction</b>	<b>Françoise Jaquet</b> Head of Division Clinical Trials
9:20 – 9:50	<b>Medicinal products – Clinical trial application / 1<sup>st</sup> part</b> <i>Submission dossier</i>	<b>Christine Hug-Michel</b> Clinical Study Reviewer, Division Clinical Trials
9:50 – 10:20	<b>Medicinal products – Clinical trial application / 2<sup>nd</sup> part</b> <i>Pharmaceutical Quality Dossier / GMP</i>	<b>Verena Gafner</b> Clinical Study Reviewer, Division Clinical Trials
10:20 – 10:50	<b>Medicinal products – Submission of changes and reporting</b> <i>Trial completion, trial discontinuation or interruption, final study reports</i>	<b>Kirsten Leidreiter</b> Clinical Study Reviewer, Division Clinical Trials
10:50 – 11:00	<b>Befristete Bewilligung</b>	<b>Lada Leyens</b> Clinical Study Reviewer, Division Clinical Trials
11:00 – 11:15	<i>Coffee Break</i>	
11:15 – 11:30	<b>Medicinal products – Safety aspects</b> <i>SUSARs, RSI, submission</i>	<b>Charles Senessie</b> Clinical Study Reviewer, Division Clinical Trials
11:30 – 12:00	<b>GCP inspections</b> <i>General GCP-inspection procedures, typical inspections findings, expectations and handling of CAPA Plans</i>	<b>Simone Ferbitz-Scheurer</b> GCP/GVP Inspector, Division Clinical Trials
12:00 – 12:30	<b>Advanced therapies – Specificities</b>	<b>Petra Kempna Bukovac</b> Quality Reviewer, Unit Transplants
12:30 – 13:00	<b>Medical devices – Specificities</b>	<b>Isabel Scuntaro</b> Scientific Officer, Division Medical Devices
13:00 – 14:00	<i>Lunch Break</i>	
14:00 – 16:00	<b>Workshops (participation at 2 workshops possible)</b>  - IMP quality - IMP safety - GCP inspections	} To be defined
16:00 – 16:30	<b>Questions and answers</b>	<b>All</b>
16:30 – 16:45	<b>Closing remarks</b>	<b>Françoise Jaquet</b> Head of Division Clinical Trials

## Further information

Language: English

Fees: None

Participants: This symposium is designed to train 1-2 persons per organisation, in order to enable these persons to train others locally (“Train-the Trainer” principle)

Other: The presentations will be made available to the participants in pdf-format.

Certificate A Certificate of Attendance will be distributed at the end of the symposium.

## Continuous education credits given by the medical associations

- Swiss Society of Pharmaceutical Medicine (SGPM/ASMP): 6 points
- Swiss Association of Pharmaceutical Professionals (SwAPP): 6 points
- Swiss Society of Clinical Pharmacology and Toxicology (SSCPT) 6 points
- Swiss Association of Public Health Administration and Hospital Pharmacists (GSASA) 50 points (for hospital pharmacy and clinical pharmacy)