

Venue



Kursaal Bern / Hotel Allegro
Kornhausgasse 3
3000 Bern
www.kursaal-bern.ch

Arriving by train:

From central train station Tram No. 9 towards "Guisanplatz", Tram stop "Kursaal"

Arriving by car:

- Highway exit "Bern-Wankdorf"
- Follow the sign "Zentrum" into Papiermühlestrasse
- Continue you reach the 3rd crossing, turn right into Viktoriastrasse and follow sign "Hotel Allegro / Kursaal"
- At Viktoriaplatz, turn left into Kornhausstrasse
- Hotel Allegro / Kursaal is situated on the right side

Parking

The parking fee for 24 hours is CHF 24.--

Be actively involved!

Send specific questions you would like to have discussed to swapp2012@association-services.ch prior to the meeting.

Registration

You can register now by sending your contact details and preferred Workshop number to swapp2012@association-services.ch or login to the events section at www.swapp.ch/events for updated information.

Fees:

- SwAPPMembers CHF 100.-
if registered prior to the meeting
- Non-SwAPP members CHF 200.-
and on-site registration for all

Please note that the number of participants is limited to 150 persons

SwAPP/SGPM accredited: **3.5 credit points**



Exchange Expertise

5th SwAPP Experts Exchange Expertise Meeting

Thursday, March 15th 2012

Realise the Future of Clinical Research in Switzerland

Kursaal Bern/
Hotel Allegro
Bern

Programme

Invitation

Dear Members and Friends of SwAPP

Switzerland's position as an important clinical research location in global programs deserves attention. How can we redress any adverse trends and stay attractive in a highly competitive environment?

Research locations globally have new regulatory challenges to think of. Both EMA and FDA recently initiated guidance on risk-based approaches in clinical research. Furthermore, EMA is starting the implementation of the adapted clinical trial directive. These changes will influence the way of performing clinical research, also in Switzerland. In addition, the new Swiss law on research involving humans tries to clarify and streamline processes towards more efficiency and professionalism.

We invite various experts and stakeholders to present their know-how and opinion about the future direction of clinical research in Europe and Switzerland. As usual, Swiss authorities will give updates on recent changes in the field of regulatory affairs and clinical trials.

For all members of the Swiss Association of Pharmaceutical Professional (SwAPP) the annual General Assembly will be held just before the ExEx meeting. If you are not yet a SwAPP member, we cordially invite you to join us. You can find an on-line application form at www.swapp.ch.

The SwAPP board is looking forward to meeting you in Bern.

Program Directors

Annette Magnin Dr Daniela Gunz

Agenda

13:00 SwAPP General Assembly
(SwAPP members only)

Plenary Session

14:00 Welcome and General Introduction: Clinical research in Switzerland and the industry – challenges and opportunities

Manfred M. Heinzer, General Manager,
Roche Pharma (Schweiz) AG, Basel

14:20 Law on research involving humans and related ordinance - Update on current status

Brigitte Meier, Leiterin Sektion Forschung
am Menschen und Ethik,
Bundesamt für Gesundheit (BAG), Bern

14:45 Where is Europe heading? Expected update of the EU clinical trial directive

Alexander Roediger, Director
European Union Affairs,
MSD (Europe) Inc. Belgium

Panel Discussion

Implications for Switzerland from an
industry and authority perspective
Moderator: Walter Hölzle, vips

15:20 Trend: Risk-based quality management in clinical trials - where is EMA (and FDA) going?

Jacques Demotes-Mainard,
Coordinator, European Clinical Research
Infrastructures Network (ECRIN), Paris

Panel Discussion

Implications for Switzerland from an
industry and authority perspective
Moderator: Walter Hölzle, vips

16:20 Coffee Break

Parallel Experts Workshops

16:50 Workshop 1: Clinical Trials

Latest news on procedures from
Swissmedic and AGEK

Françoise Jaquet, Swissmedic

Dorothy Pfiffner, AGEK

Moderator: Annette Magnin, SwAPP

16:15: Workshop 2: Regulatory Affairs

Important news on regulatory procedures
and update on Swissmedic's new
administrative ordinance instructions.

Speaker from Swissmedic, tba

Speaker from Industry, tba

Moderator: Doris Penna, SwAPP

18:00 Networking Apéro

Panel / Experts

Dr. Françoise Jaquet

Head of Division Clinical Trials, Swissmedic

Prof. R. Maurer, Member of the Board, AGEK

Speaker from BAG, tba

Register online and save at
www.swapp.ch/events

