The Swiss TPA: Supporting Therapeutic Innovation?

The new Therapeutic Products Act (TPA) entered into force on January 1, 2019, with the objectives to accelerate market approvals and patient access to innovative products. What has been the experience since the revision date? The 13th ExEx symposium focuses on the new TPA key aspects towards innovation and the meaning of global synergies, including the interaction of Swissmedic with international Health Authorities. In the context of digitalization of the Health Care sector, a session will also address some of the necessary management skills.

SwAPP events lays great emphasis on practical and lively discussions to favor exchange of ideas and experience between all participants, as well as the development of your career.

12:45 Reception and Coffee
13:00 Welcome - Frank van den Ouweland, President, SwAPP (Geneva, CH)
13:15 Onboarding Session
   The revised TPA: a more flexible regulatory framework for new technologies?
   Simon Dalla Torre, Head of Regulatory Operations & Development, Swissmedic (Bern, CH)
   Corinne Wenger, Head of Drug Regulatory Affairs, Roche (Basel, CH)
   Doris Penna, Regulatory Affairs Manager, Eli Lilly (Geneva, CH)
14:00 Parallel focus Sessions

   Safety signals management
   Renate Essen,
   Head Risk Management, Swissmedic (Bern, CH)
   Karin Vermot-Gaud Fornier,
   Sr Drug Safety Officer, Affliate Responsible Pharmacovigilance Person (RPV), Eli Lilly (Geneva, CH)

   Tissue-agnostic therapy: innovation in oncology
   Claudia Stadelmann,
   Director of Regulatory Affairs, MSD Merck Sharp & Dohme AG (Lucerne, CH)
   Vanya Loroch,
   CEO, Loroch CTLS (Essertines-sur- Rolle, CH)
   Frank van den Ouweland,
   President, SwAPP (Geneva, CH)

   Developing digital-age management skills
   Edward Mulder,
   Head Organization & Information Services, IVF Hartmann AG (Neuhausen, CH)
   Pierre Crivelli,
   Director of Digital Governance Services and Country Manager CH, PQE Group (Mendrisio, CH)
   Ana Brake, Member of the Board, SwAPP (Zurich, CH)

15:00 Coffee break
15:30 Parallel focus Sessions (repetition)
16:30 Outlook Session
   Building up trust in international regulations: the need for synergy and collaboration
   Rebecca Wood, Former Chief Counsel FDA; Partner & Co-Lead, Food Drug & Regulatory Practice,
   Sidley Austin (Washington, US)
   Swissmedic (Bern, CH) – Speaker to be confirmed

17:15 Concluding remarks

17:30 – 20:00 Networking Cocktails
18:00 – 19:00 SwAPP General Assembly
Registration

Due to the Covid-19 pandemic challenges we have implemented a pre-registration process. To benefit from an early bird rate register by Apr, 13th. SwAPP is monitoring the situation carefully and will postpone the event if required. Cancellation of preregistrations will follow our general cancellation policy unless the event is postponed.

- Please register via “Xing Events”; see here
- Payment is required prior to the symposium.
- To facilitate the organization, please indicate on the registration platform if you join the networking cocktail.
- The participant fee includes break and apéro costs.
- At events, SwAPP is taking photographs and videos of our conferences and courses (both online and in print).
  By registering for the meeting you agree that you accept the further use of the photographs and/or videos.

Participation fees

SwAPP Members          CHF 300,- (Early bird seats available up to Apr, 13th)
                        CHF 400,-
Non-Members             CHF 450,- (Early bird seats available up to Apr, 13th)
                        CHF 550,-
Students (basic studies) CHF 100,-

Venue

Sorell Ador Hotel, Laupenstrasse 15, 3001 Bern

Cancellation Policy

You may cancel 10 business days before the meeting and receive a full refund minus the cancellation fee of CHF 50.- Cancellations less than 10 business days before the symposium date will not be refunded.

Accreditation

This event is accredited with 4.5 credits by SwAPP/ SGPM.

Learning Objectives

To familiarize with key aspects of the revised Swiss TPA towards innovation
To understand the meaning of risk management in pharmacovigilance
To become acquainted with the tissue-agnostic drug development approach
To benefit from the feedback of key stakeholders regarding the revised TPA implementation
To become aware of the new skills required to develop innovative products in the digital-age

Target Audience

New comers and experienced professionals interested in the development of therapeutic products, regulatory affairs, clinical affairs, quality, medical affairs, market access, process development; working in the Industry, Contract Research Organisations, Competent authorities, Notified bodies, Ethics Committees or Academia.

Friends of SwAPP

The ExEx Symposium is not sponsored. SwAPP benefits only from the support of other associations who publish the event on their communication platform without financial compensation.