12th SwAPP ExEx Symposium
19 March, 2019
Solothurn

MAKING DRUGS WORK BETTER: COMBINATION WITH DELIVERY SYSTEMS

Landhaus, Landhausquai 4, CH-4500 Solothurn

Drug-device combination products represent the next wave of drug delivery systems with incredible advantages for patients but are of high complexity in terms of design and development. In this context, the SwAPP has elaborated an Exchange Expertise event for pharma professionals and academics, who are interested to learn more about the way of improving drug efficiency and safety, as well as patient compliance, by integrating the latest medical device technologies.

Programme

11:00 **SwAPP General Assembly and election of the new Board** (for SwAPP members, guests are welcomed)

13:00 **ExEx symposium: Reception and Coffee break**

13:15 **Welcome**
Mirjam Eglin, President, SwAPP (Bern, CH)

13:30 **Plenary Session**

- **Innovation in drug delivery: from energy activated drugs to connected medical devices**
  Ian Thompson, Vice President Business Development, Ypsomed (Bern, CH)
- **Human-centered design approach in development of drug delivery systems**
  Cédric Gysel, Manager Health Care Solutions Design, Johnson & Johnson (Zurich, CH)
- **Challenges in developing combination products**
  Manfred Maeder, Head of Device Development & commercialization, Biologics Technical Development & manufacturing, Novartis (Basel, CH)

15:30 **Coffee break**

16:00 **Parallel breakout sessions**

N°1 - Regulatory	N°2 - Clinical	N°3 - Innovation
Impact of the MDR on Combination Products *- Doris Penna, Regulatory Affairs Manager, Eli Lilly (Geneva, CH)* *- Andrea Sparti Regulatory Affairs Manager, Cendes+Métaux (Biel, CH)* *- Andreas Balsiger Betts, Senior Advisor, Sidley Austin (Geneva, CH)*	**Clinical development: Combination products *vs* Drugs** *- Raquel Billiones, Senior Director, Head of Medical Writing, Takeda Vaccines (Zurich, CH)* *- Olivier Goarnisson Counsel, Sidley Austin (Geneva, CH)* *- Frank van den Ouweland, Consultant, Pharmaceutical Medicine (Geneva, CH)*	**Drug/Device mutual understanding: the case of technology transfer** *- Laurent-Dominique Piveteau, CEO, Debiotech (Lausanne, CH)* *More to be announced…*

17:00 **Parallel breakout sessions (repetition)**

17:55 **Concluding remarks**
Representative of the new Board, SwAPP (Bern, CH)

18:00 **Closing Networking Apéro**

Breakout sessions updates, please check here: https://swapp.ch/events/swapp-events/

Registration

- Please register via “Xing Events”; see **here**
- Registration and payment are required prior to the symposium.
- To organise the break between General Assembly and ExEx symposium, and the closing networking apéro, please indicate if you plan to join also the General assembly (without charges) and/or the closing apéro. 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 400,- (see for early bird options)
Non-Members	CHF 550,-
Students (basic studies)	CHF 100,-

Groups, please contact us: swapp@swapp.ch, re: ExEx 2019 groups

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.

Venue

Landhaus: Landhausquai 4, CH-4500 Solothurn
The Landhaus is situated in the historical center of Solothurn, directly at the Aare, 550m footway from SBB main station via Hauptbahnhofstrasse, Kreuzackerbrücke.

Accreditation

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

Learning Objectives

- To familiarize with some of the latest innovations in the field of drug delivery devices
- To understand how such systems can improve drug efficacy and safety
- To be aware of the challenges to face when integrating delivery devices in drug development
- To become acquainted with some key regulatory requirements of drug-device combination products
- To have a better understanding of both adjacent legislations, including the new EU Medical Device Regulation

Target Audience

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

If you are not a SwAPP member yet, benefit from the reduced registration fee by signing up for membership at www.swapp.ch