



University
of Basel

Faculty of
Medicine



Bringing Medical Devices & Combination Products to the Market

Continuing Education Series:
Frontiers in Drug Development

**Biozentrum,
Spitalstrasse 41,
4056 Basel**

Thursday, February 9, 2023
08:30 am – 16:15 pm

ECPM[®]
European Center of Pharmaceutical Medicine

**CONTINUING
EDUCATION**

Under the auspices of
EUCOR, the European Campus
IFAPP, Int. Federation of Associations of Pharmaceutical Physicians
and Pharmaceutical Medicine

Accredited by SwAPP/SGPM and FPH SPITAL
Recognized as PharmaTrain Centre of Excellence



Invitation

Over the past couple of years, digitalization has changed the pharma industry enormously and Medical Devices and Combination Products are becoming increasingly important. In this seminar, we will not only discuss the development and regulation of medical devices and combination products, but also the further essential steps to bring and maintain these products on the market. Moreover, we will get insights into guidance documents and information about what is needed and done in case there are quality challenges and recalls.

During this day, you will have the chance to discuss the advantages and risks of combination products regulated as medical devices and to see this important topic from the perspective of health insurance companies.

Join this seminar to discuss challenges and solutions on this interesting topic and get in close dialogue with key stakeholders.

We would like to invite you and your colleagues to our seminar.



A handwritten signature in black ink, appearing to read 'Thomas Szucs'.

Prof. Dr. Thomas D. Szucs
Director



A handwritten signature in black ink, appearing to read 'Annette Mollet'.

Dr. Annette Mollet
Head of Education & Training



A handwritten signature in black ink, appearing to read 'Evelyn Fischer'.

Evelyn Fischer
Course Director

Bringing Medical Devices & Combination Products to the Market

February 9, 2023

Biozentrum, Spitalstrasse 41, 4056 Basel

Chairperson: Juliette E. Cook

08:00

Registration for external participants

Developing and Testing of Combination Products

Manfred Mäder, Novartis Pharma AG, Basel

Regulation of Medical Devices and Combination Products in the EU

Shayesteh Fürst-Ladani, SFL Regulatory Affairs & Scientific Communication Ltd., Basel

10:00 – 10:30

Coffee Break

Impact of IVDR Legislation on Clinical Development

Marie Claire Beurier, F. Hoffmann-La Roche AG, Basel

Design of Clinical Medical Devices Investigations and Approvable Endpoints

Andreas Beust, GCP-Service International Ltd. & Co. KG, Bremen

12:00 – 13:00

Lunch

How to Maintain your Medical Device on the Market and Fulfill Ongoing Obligations in the post-launch Phase

Juliette Cook, Implantica Management AG, Zug

Guidance Documents for Medical Devices

Tom Melvin, Trinity College Dublin, Dublin

14:30 – 14:45

Coffee Break

Issue Management: Quality Defects and Recalls

Benjamin Mutschlechner, Pfizer Deutschland GmbH, Freiburg

Medical Devices from the Perspective of Health Insurance Companies

Ivan Tomka, Helsana Versicherungen AG, Zurich

About Frontiers in Drug Development Seminars

ECPM offers one day seminars on new trends and developments in drug development science. These seminars provide the opportunity to integrate work and further education, to discuss with experts face-to-face and to build an international network. They take place on the fourth day of each of the six modules of the ECPM Diploma Course and are mandatory for students taking the Diploma Course. Additionally they are open to our alumni and other interested scientists and can be booked separately.

Learning Outcomes

Participants will learn about the:

- Technologies, Computer Simulation and Modeling, Personalized Medicine, Genomics, Biologicals and Biosimilars, and Advanced Therapeutics
- Regulatory Agency updates from FDA, EMA and Swissmedic
- Ethical, Economic and Epidemiological Considerations and Concepts in Drug Development

Date and Venue

February 9, 2023
University of Basel
Biozentrum
Spitalstrasse 41
4056 Basel
Switzerland

Registration

Via our homepage www.ecpm.ch or
www.ecpm.ch/frontiers-in-drug-development-s5

Deadline for Registration: January 30, 2023

Credits

Six workshops over a period of two years, which equal 1 ECTS credit. Accredited as continuing education with eight credits by the Swiss Society of Pharmaceutical Medicine (SGPM) and the Swiss Society of Pharmaceutical Professionals (SwAPP). Accredited with 50 FPH-points in hospital pharmacy by the Swiss Society FPH Spital (Fachgesellschaft FPH Spital).

Fee

Course fee including certificate and electronic course material is CHF 680 and CHF 580 for ECPM Alumni and SwAPP/SGPM members. The reduced fee for participants from academia and nonprofit organizations is CHF 210.

After registration you will receive an invoice. For short notice registration, please send a copy of the money transfer to ecpm@unibas.ch.

Cancellation Policy

Refund of fee will be given if cancellation is received in writing before the deadline for registration, after this date no refund can be given. Speakers are subject to change without notice.

Seminar Organizer

This seminar is organized by the European Center of Pharmaceutical Medicine, University of Basel, Switzerland.

Educating Talents since 1460.

University of Basel
ECPM
Institute of Pharmaceutical Medicine
Klingelbergstrasse 61
4056 Basel
Switzerland

www.ecpm.ch

