

Emulsions & Gels

Development, Manufacture & Control of Dermatopharmaceuticals and Cosmetics

SPEAKERS:



Dr Michael Drechsler
GP Grenzach Produktions GmbH (Bayer AG)



Dr Thomas Meindl
Labor LS



Prof Dr Reinhard Neubert
University of MLU Halle, IADP (Institute for Applied Dermatopharmacy)



Dr François-Xavier Simon
BASF



Prof Dr Norbert Willenbacher
Karlsruhe Institute of Technology (KIT)



20-21 November 2019, Hamburg, Germany

HIGHLIGHTS:

- GMP Aspects relevant to semisolids
- Manufacturing & filling of semisolids
- Colloidal carrier systems
- Biopharmaceutical & rheological characterization
- Application & use of emulsifiers
- Microbiological & Stability testing including handling of OOS/OOT

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Background & Objectives

A lot of pharmaceutical products, cosmetics and food products are emulsions & gels. Regarding the production of pharmaceutical semi-solid preparations, the common GMP (Good Manufacturing Practice) concepts of validation and qualification have to be applied (i.e. EU GMP guidelines including Annex 9 and 15).

Semi-solid products have some characteristics that are different compared to other dosage forms (e.g. solid oral dosage forms). Due to the intrinsic effect of the vehicle and the influence of the formulation on the release of active ingredients (and the subsequent absorption), the final formulation (including packaging) should be defined early in the pharmaceutical development process. Comprehensive analytical, microbiological and stability testing contributes to that.

Additionally, since August 2013, important tools for the biopharmaceutical characterization of drug release are contained in the United States Pharmacopeia (USP) Chapter <1724> "Semisolid Drug Products – Performance Tests". Furthermore, rheology plays a significant role in the determination of a formulation's flow properties (and for the characterization of semi-solid raw materials, like for example petrolatum, lanolin), during development, in-process-control (IPC), final end-product testing & release as well as in stability testing. The knowledge of rheological properties is essential for the production and filling of semi-solid preparations. Moving forward, the USP recently published two drafts for new USP Chapters <915> "Measurement of Structural Strength of Semisolids by Penetrometry" and <1912> "Measurement of Hardness of Semisolids" regarding the characterization of viscoelastic properties of semi-solid preparations (Pharmacopeial Forum PF 43(2) [Mar.–Apr. 2017]).

These and other relevant topics will be presented and discussed in this training.

This training aims at explaining the pharmaceutical, biopharmaceutical and technological aspects of various semi-solid dosage forms for topical use.

Formulation concepts (including the use of emulsifiers and colloidal carrier systems), GMP aspects and the industrial manufacture/ filling of semi-solid formulations are clearly illustrated. The rheological characterization as well as microbiological and stability testing will be covered.

Target Audience

This course is directed at specialists and executives in research, development, production, quality control and quality assurance involved in the manufacturing, packaging, testing, release and authorization of pharmaceutical semisolids and cosmetic preparations.

Programme

Industrial manufacturing of semisolids – GMP aspects

- GMP
- Validation
- Risk assessment
- Change control

Relevant semisolid formulations

- Technology of semisolid standard formulations relevant in Dermatopharmaceutics as well as in Cosmetics
- Substantial excipients for the preparation of the semi-solid formulations
- Colloidal carrier systems to enhance penetration of highly lipophilic/ hydrophilic drugs and cosmetic actives (e.g. ceramides, peptides)

Manufacturing of semisolids

- Process
- Mixer
- CIP/SIP
- IPC

Filling of semisolids

- Process
- Filling machines
- Storage container
- IPC

Biopharmaceutical characterization of semisolid formulations

- Methods and procedures to measure drug release from semisolid formulations
- Methods for measuring drug penetration into the human skin
- Real examples for each method
- Regulatory aspects

Rheology of emulsions

- Basic phenomena
- Experimental characterization techniques
- Rheology and composition of emulsions and dispersions
- Technical application examples

Microbiological tests and requirements

- Regulatory requirements for pharmaceutical products versus cosmetics
- Bioburden
- Specific tests (aW value determination)
- Challenges & Interpretation of test results
- Efficacy of antimicrobial preservation

The Application and Use of Excipients – Insights and Challenges

- Understanding the importance of emulsifiers/surfactants in formulations
- Influence of excipient selection on performance
- Chemical and physical stability of ingredients
- Simple analytical techniques for evaluation

Stability testing

- Design & Control of stability studies
- In-use stability

Handling of OOS and OOT results

- Microbiological tests: When is a result a OOS/OOT result?
- How to handle OOS and OOT results?
- How helpful are expert opinions in this context?

Speakers



Dr Michael Drechsler

*GP Grenzach Produktions GmbH (Bayer AG)
Head of Production (Sterile Semisolids)*

Michael Drechsler studied pharmacy at Regensburg University (Germany) and earned his PhD from Freiburg University (Germany) at the Institute of Pharmaceutical Technology and Biopharmaceutics. Since 2013 he is working for GP Grenzach Produktions GmbH (BAYER AG), first as Product Life Cycle Manager in the Department of semisolids and solids and then as GMP Compliance Manager in the Department of sterile semisolids (manufacturing and filling). He is Head of production in the Department of sterile semisolids (manufacturing and filling) since 2015.



Dr Thomas Meindl

Labor LS SE & Co. KG, Division Manager

Thomas Meindl is a trained biologist who performed his PhD on novel peptide receptors at the FMI (Novartis) in Basel, Switzerland. From there he moved to a drug discovery company (Sympore, Germany) in order to discover new drug entities (patent in 2002). Then he performed clinical studies for skm oncology, Germany, until he moved to Labor L+S AG, Germany, in 2005. Here he worked as division manager of various departments (Assays, Endotoxins, R&D, Molecular biology, Disinfectant testing and computerized systems) until today.



Prof Dr Reinhard Neubert

*University of MLU Halle, Vice-Chairman IADP
(Institute for Applied Dermatopharmacy)*

Reinhard Neubert is Professor for Biopharmaceutics and Pharmaceutical Technology at the Martin-Luther-University (MLU, Halle, Germany). From 1996-2003 he was the speaker of the Graduate Program

“Transport in biological systems” of the German Research Community. Since 2000 he is appointed reviewer of the German Drug Administrations (BfArM and BVL). From 1996-2014 he was Chairman of the Institute of Applied Dermatopharmacy (IADP) at the MLU and since 2016 he is Vice-Chairman of IADP. His Research interests are: Drug transport, Dermal drug delivery, Colloidal drug carrier systems, Biosensors based on quartz microbalance, Drug analysis based on capillary electrophoresis and HPLC mass spectrometry, food-drug interactions, Molecular structure of the stratum corneum lipids. He is author of more than 400 publications in international scientific journals.



Dr François-Xavier Simon

Technical Service Manager BASF Pharma Solutions

François-Xavier studied chemistry at the University of Metz (France) and achieved a doctorate in Chemistry and Physico-Chemistry of self-assembled materials from the University of Strasbourg (France) in 2006. He joined BASF R&D to work on polymers in 2007 and moved towards the Market Development of BASF France in 2009 where he was responsible for technological survey for venture capital investment. Since 2012 he is part of the Technical Service Manager within BASF Pharma Solutions and is responsible of the Skin Delivery Platform of BASF Pharma Solutions in Europe.



Prof Dr Norbert Willenbacher

*Karlsruhe Institute of Technology (KIT), Head of the
Institute of Mechanical Process Engineering and
Mechanics*

Norbert Willenbacher is head of the Institute of Mechanical Process Engineering and Mechanics at Karlsruhe Institute of Technology (KIT) since 2004. He received his diploma degree in Physics and his PhD from the University of Mainz. After his dissertation at the Max-Planck-Institute for Polymer Research he joined BASF SE as a research associate in the fields of rheology of complex fluids and adhesion of soft polymers for 15 years. He is president of the German Society of Rheology, assigned member of the ProcessNet Technical Committee on Rheology, and member of the Editorial Board of *Rheologica Acta*.

Social Event



In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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Reservation Form (Please complete in full)

Emulsions & Gels

20-21 November 2019, Hamburg, Germany

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Title, first name, surname

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Department

Important: Please indicate your company's VAT ID Number

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Date

Wednesday, 20 November 2019, 9.00 to 17.00 h
(Registration and coffee 8.30 to 9.00 h)
Thursday, 21 November 2019, 9.00 to 13.30 h

Venue

Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg
Phone +49 40 22 63 62 0
Email hamburg@barcelo.com

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on first day, business lunch on second day and all refreshments.
VAT is reclaimable.

Accommodation



Reservation should be made directly with the hotel. Early reservation is recommended. If booking via the website www.barcelo.com, participants receive a discount of 10% on the daily room rate. You will receive a discount code when you register for the course.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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