20 YEARS ECA Academy Your GMP/GDP Information Source

Emulsions & Gels

Development, Manufacture & Control of Dermatopharmaceutics and Cosmetics

SPEAKERS:

Dr Michael Drechsler
GP Grenzach Produktions GmbH (Bayer AG)

Christian Lomb
Labor LS

Dr Thomas Meindl
Labor LS

Dr Claude Oelschlaeger
Karlsruhe Institute of Technology (KIT)

Prof Dr Miriam Pein-Hackelbusch
University of Applied Sciences and Arts Ostwestfalen Lippe

Dr François-Xavier Simon
BASF

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

This education course is recognised for the ECA GMP Certification Programme „Certified Pharmaceutical Development Manager". Please find details at www.gmp-certification.eu

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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 Semisolids
- Classification according to Ph. Eur.
- Dispersions and phases
- Examples of relevant excipients
- What about nanocarriers?

Manufacturing of semisolids
- Process
- Mixer
- CIP/SIP
- IPC

Filling of semisolids
- Process
- Filling machines
- Storage container
- IPC

Biopharmaceutical aspects of semisolids
- In vitro drug release
- Drug penetration into the human skin
- The interplay between vehicle and drug

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.

Christian Lomb

Labor LS SE & Co. KG
Christian is a trained biologist (University of Würzburg, Germany). He worked in a diagnostic laboratory prior to starting his work at LS as project leader for antimicrobial challenge tests (efficacy of antimicrobial preservation) and microbial enumeration tests.

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.

Dr Claude Oelschlaeger

Karlsruhe Institute of Technology (KIT)
Institute of Mechanical Process Engineering and Mechanics
Since 2006, Claude Oelschlaeger is Senior Scientist at the Institute of Mechanical Process Engineering and Mechanics at KIT. After his dissertation (University of Strasbourg, France) based on rheology and light scattering of surfactant solutions, he joined the Max-Planck-Institute for Polymer Research in Mainz as a postdoc working on method development and non-linear rheology of block copolymers. Currently, he is responsible for the research activities in the area micro- and macrorheology of surfactant and biopolymer solutions, networks and gels.

Prof Dr Miriam Pein-Hackelbusch

University of Applied Sciences and Arts Ostwestfalen Lippe, Germany, Department Life Science Technologies
Miriam Pein-Hackelbusch studied pharmacy at the university of Hamburg from 2000-2004 and got licensed as pharmacist in 2005. In 2008 she gained her doctorate for pharmaceutical and medicinal chemistry from the Heinrich-Heine-University Düsseldorf. In 2010 she was honored for outstanding teaching. Prof Pein-Hackelbusch was appointed as endowed (SEPAWA) professor for technology of cosmetics, detergents and pharmaceutics at the University of Applied Sciences and Arts Ostwestfalen Lippe in 2016 and received the venia legendi (Habilitation) for pharmaceutical technology and biopharmacy from the Heinrich-Heine-University Düsseldorf in 2019.

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.

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Emulsions & Gels
20-21 November 2019, Hamburg, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

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General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- until 2 weeks prior to the conference 10 %,
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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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