Speakers

Dr Michael Drechsler
Bayer Consumer Care, Switzerland

Jürgen Martin
Martin-Consulting, Germany

Dr Claude Oelschlaeger
Karlsruhe Institute of Technology (KIT), Germany

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

Dr François-Xavier Simon
BASF, France

Emulsions & Gels

Development, Manufacture & Control of Dermatopharmaceutics and Cosmetics

Live Online Training on 17/18 March 2021

Highlights

- GMP Aspects relevant to semisolids
- Manufacturing & filling of semisolids
- Colloidal carrier systems
- Biopharmaceutical & rheological characterization
- Application & use of emulsifiers
- Stability testing
- Efficacy of antimicrobial preservation
- Handling of OOS/OOT

Programme

Background

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.

In 2018, the EMA published the draft *Guideline on quality and equivalence of topical products*. The guideline relates to locally applied and locally acting medicinal products for cutaneous use. Specific guidance is provided:

- On the quality of topical products not covered by other guidelines.
- On equivalence testing of topical products in lieu of therapeutic equivalence clinical trials.

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"*. A reference to <1724> is made in USP <3> *"Topical and Transdermal Drug Products - Product Quality 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 introduced two 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 (to be official on 1-May-2021).

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

Objectives

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 Live Online Training 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 Day 1

Provisional timetable, the actual schedule may vary depending on the situation.

09.00 - 09.15 h Welcome/Introduction

09.15 - 10.00 h Industrial Manufacturing of Semisolids – General Aspects

- GMP
- Validation
- Scale-up
- Risk assessment
- Change Control

10.00 - 10.45 h Manufacturing of Semisolids – Practical Aspects

- Process
- Mixer
- CIP/SIP
- IPC
- Troubleshooting

10.45 - 11.00 h Break

11.00 - 12.15 h Relevant Semisolids

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

12.15 - 12.45 h Q&A Session 1

12.45 - 13.45 h Break

13.45 - 14.30 h Filling of Semisolids

- Process
- Filling machines
- Storage container
- IPC
- Troubleshooting

14.30 - 15.30 h Biopharmaceutical Aspects of Semisolids

- EMA Draft Guideline on quality and equivalence of topical products
- In vitro drug release
- Drug penetration into the human skin
- The interplay between vehicle and drug

15.30 - 15.45 h Break

15.45 - 16.30 h Stability Testing & Efficacy of Antimicrobial Preservation

- Stability Testing
  - ICH requirements
  - Design of stability studies
  - Matrixing & Bracketing
  - Interpretation of test results & statistical analysis
- Efficacy of antimicrobial preservation
  - Requirements according to Ph. Eur. and USP
  - Relationship between the efficacy of antimicrobial activity and in-use stability
  - Practical examples

16.30 - 17.00 h Q&A Session 2

Programme Day 2

09.00 - 10.00 h Rheology of Emulsions

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

10.00 - 11.00 h 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

11.00 - 11.15 h Break

11.15 - 12.00 h Handling of OOS and OOT Results

- OOS-Results
  - Requirements according to the FDA-OOS-Guideline
  - What needs to be considered with regard to complex matrices?
  - Examples
- OOT & OOE-Results
  - Requirements for investigation
  - Example of a risk-based approach
- Adverse Trends
  - Trends and possible root cause

12.00 - 12.30 h Q&A Session 3

Speakers

Dr Michael Drechsler, Bayer Consumer Care AG, Switzerland

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 BAYER AG in various positions. He started as Product Life Cycle Manager in the Department of Semisolids and Solids, later on as GMP Compliance Manager & Head of Production in the Department of sterile semisolids (manufacturing and filling) and in the Department of bulk manufacturing & Filling/Packaging of Semisolids and Solids, respectively. Since 2020 he took over responsibility as Technical Manager for External Manufacturing.

Jürgen Martin, Martin-Consulting, Germany

Jürgen Martin has more than 25 years of experience in pharmaceutical industry and quality control. After his education at the University of Konstanz he has held different leading positions focusing on quality control topics at Byk Gulden, Altana Pharma and Nycomed. Between 2011 and 2019 he was building up and heading the quality control of the BIPSO GmbH. Since 2019 he is operating his own consultancy and software development office.

Dr Claude Oelschlaeger, Karlsruhe Institute of Technology (KIT), Germany

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

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, BASF, France

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.

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Live Online Training on 17/18 March 2021

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Date of the Live Online Training
Wednesday, 17 March 2021, 9.00 – 17.00 h
Thursday, 18 March 2021, 9.00 – 12.30 h

All times mentioned are CET.

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Fees (per delegate, plus VAT)
ECA Members € 1,590
APIC Members € 1,690
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Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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PE/16112020