ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

Speakers

Dr Michael Drechsler
Bayer Consumer Care,
Switzerland

Dr Ingrid Mecklenbräuker,
Novartis Pharma Stein,
Switzerland

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 10/11 October 2023

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
- Microbiological requirements

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, 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". In a draft version of chapter <1724>, published in PF 48(3), the scope has been expanded to include in vitro release test (IVRT) as well as in vitro permeation test (IVPT) methods, with discussions on experimental design, method development, and validation.

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 introduced two new USP Chapters <915> *"Measurement of Structural Strength of Semisolids by Penetrometry"* and <1912> *"Measurement of Hardness of Semisolids"* (an updated title was proposed in PF 48(3) to better describe the content of the chapter: Measurement of *Yield Stress*) regarding the characterization of viscoelastic properties of semi-solid preparations.

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

Relevant Semisolids

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

Industrial Manufacturing of Semisolids – General Aspects

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

Manufacturing of Semisolids – Practical Aspects

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

Q&A Session 1

Filling of Semisolids

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

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

Microbiological Tests and Requirements

- Pharmacopoeial requirements
- Acceptance level & Interpretation of test results
- Efficacy of antimicrobial preservation
  - Requirements according to Ph. Eur. and USP
  - Relationship between the efficacy of antimicrobial activity and in-use stability

Q&A Session 2

Programme Day 2

Rheology of Emulsions

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

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

Aspects to Consider for Stability Testing

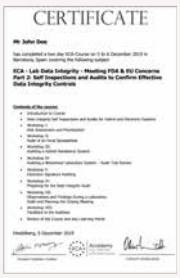
- ICH requirements
- Design of stability studies
- Matrixing & Bracketing
- What needs to be considered with regard to complex matrices?

Q&A Session 3

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „… All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,…". This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.


CERTIFICATE

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropiate supplement to acquire this qualification. This Live Online Training is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org https://www.gmp-compliance.org/recordings.

Speakers

Dr Michael Drechsler, Bayer Consumer Care, 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.

Dr Ingrid Mecklenbräuker, Novartis Pharma Stein, Switzerland

Ingrid Mecklenbräuker studied biology at the University of Vienna and earned her PhD at the University of Cologne. In 2011 she joined Eurofins | GeneScan GmbH where she was involved in building up the microbiological division and validation of new molecular detection methods for pathogenic microorganisms in food. In 2013 she joined Novartis Pharma Stein AG as QC Lab Coordinator (Non-sterile Drug Products).

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 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. Since 2012 he was Technical Service Manager within BASF Pharma Solutions and responsible for the Skin Delivery Platform. Currently he is Local Sales Manager Nutrition & Health.

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Reservation Form (Please complete in full)

Emulsions & Gels - Development, Manufacture & Control of Dermatopharmaceutics and Cosmetics
Live Online Training on 10/11 October 2023

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation. **Terms of payment:** Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training
Tuesday, 10 October 2023, 9.00 – 17.00 h
Wednesday, 11 October 2023, 9.00 – 12.30 h

All times mentioned are CEST.

Technical Requirements
We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

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.

You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

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

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