APV Expert Workshop: Emulsions

- topical emulsions and creams
- parenteral emulsions
- oral emulsions



01 to 02 April 2019 Düsseldorf, Germany

Course no. 6767



Hot Topics

Target group

Management and employees from the pharmaceutical and cosmetic industry, in particular from the areas of R&D formulation and process engineering, pharmaceutical technology, development, engineering and quality assurance.

The seminar is also addressing suppliers of raw materials (excipients) or equipment in the pharmaceutical and cosmetic sector.





A seminar organised by the APV focus group Liquid and semi-solid dosage forms

Objectives

The seminar "emulsion experts" is the extension of the APV basics seminar "Praktikum Emulsionen". In this seminar, experts will give insights into the most recent developments in the field of topical, parenteral and oral emulsions and creams. This starts with fundamentals in the research area, goes on with aspects of the development and ends with production related topics.

Different speakers will also address the different formulation technologies like emulsions, liposomes as well as mixed micelles and will discuss the advantages as well as challenges. Structural properties of the formulations may have an impact on stability, efficacy and bioavailability. Relevant analytical methods such as rheology or confocal Raman spectroscopy will be presented.

Scientific committee



Karsten Köhler, Hochschule Albstadt-Sigma

Prof. Dr. Karsten Köhler's main research areas in pharmaceutical technology are the production of creams, dispersions and emulsions. He has built up his expertise through many years of research in the

field of basic research as well as application-oriented research in the pharmaceutical, cosmetics and food industries. Hereby he is represented in various committees and journals.



Gerd Kutz, Hochschule Ostwestfalen-Lippe

Dr. Kutz was appointed as a full professor for "Technology of Cosmetics and Detergents" at the University of Applied Sciences HS Ostwestfalen-Lippe, faculty of "Life Science Technologies" in

1993. Since 1997, Prof. Dr. Kutz has worked in the organization of the studies "Pharmaceutical Engineering" too and has been lecturer for "Pharmaceutical Technology" and "Quality Assurance". Prof. Dr. Kutz extended his subject area and became Chair for "Pharmaceutical Technology" as well as for Cosmetics and Detergents" in 2007. Since 2009, he is head of the APV focus group "Semisolid and Liquid Dosage Forms". Futher more He is member of many scientific societies, editorial advisory boards of several scientific journals and academic advisory councils and court-appointed expert, e.g. for the "Bundesgerichtshof" (BGH, X. Senat).



Dominique Lunter, University of Tübingen

Dominique Jasmin Lunter is a junior research group leader at the University of Tuebingen, Germany. She studied Pharmacy at the University of Tuebingen and received a Ph. D. in Pharmaceutical

Technology from the same university in 2012. Her research interests include the development of dermal formulations for the treatment of chronic skin diseases and the use of confocal Raman microscopy/ microspectroscopy to evaluate inner structure of the formulations as well as skin penetration.

Programme

Monday, 01 April 2019, 13:00 - 18:00 h

Welcome address and introduction

Karsten Köhler, Hochschule Albstadt-Sigmaringen, Germany Gerd Kutz, Hochschule Ostwestfalen-Lippe, Germany Dominique Lunter, University of Tübingen, Germany

New formulations in emulsion technology – an overview Gerd Kutz, Hochschule Ostwestfalen-Lippe, Germany

Continuous production! Also for pharmaceutical emulsions?

- Introduction
 - Batch vs. Conti
- Chemical, Physical and Mechanical Methods
- Overview over mechanical methods
- Emulsions on a chip
- Continuous approaches

Karsten Köhler, Hochschule Albstadt-Sigmaringen, Germany

Lipid excipient chemistry and critical material attributes relevant to solubility and bioavailability enhancement

- Excipients to formulate oral emulsions
- Oleo chemistry and its link to formulation performance
- Enhancing bioavailablity

Delphine Marchaud, Gattefossé, France

Lipid based formulations for enhanced oral bioavailability Sandra Klein, University Greifswald, Germany

Networking dinner

Tuesday, 02 April 2019, 08:30 - 16:30 h

"Cream 2.0". Enhancing scope, performance and robustness of emulsions through rational design

Understanding distribution processes of APIs and excipients in emulsions enables to extent the scope of creams to broader range of formulation challenges and helps to design more robust systems.

- Distribution phenomena in emulsions:
- Monitoring and understanding the distribution of APIs and critical excipients helps to improve chemical and antimicrobial stability as well as robustness.
- Emulsifiers: Consideration on how to select the appropriate emulsifier type(s) and concentrations. Effects of excess emulsifiers and limitations of the HLB concept.
- Adjusting consistency: Thickening polymers and/or low molecular weight consistency agents? Impacts on process, aging phenomena and impact of variability of excipient qualities.
- Penetration:

Modifying skin penetration without "penetration enhancers": design principles of emulsions that influence penetration.

Michael Herbig, RaDes, Germany

Lipid emulsions in Clinical Nutrition

- Clinical relevance of lipids as macronutrients
- Product composition and analysis
- Admixtures and emulsion stability

Marc Willuhn, Willuhn Consulting AB, Sweden

Liposomes

- Overview: Liposomes marketed and in clinical development (indications and application routes)
- Architecture of liposomes (SUV, MLV, stealth, targeted)
- Manufacturing of liposomes in small and GMP scale
 Integration of drug: in lipid bilayer vs. in aqueous core -> principle and limitations of remote loading, liposomal drug retention upon application, encapsulation yields
 - Limitation of up-scaling
- Liposomes for parenteral administration
 - For solubilization of poorly water soluble parenteral drugs
 Novartis case study
 - Opportunities and limitations for passive and active drug targeting of solid tumors
- Liposomes for topical administration routes
 - Potential benefits in general
 - Novartis case study

Andreas Fisch, Novartis, Switzerland

Characterization of formulation structure and CQA

- Attributes of semisolid formulations are driven by excipients. Accessing a broad excipient portfolio gives formulators flexibility while developing gels, foams, creams and other topical products
- Presentation of case studies to demonstrate the influence of excipients on the performance of skin delivery dosage forms like stability, penetration and skin feeling

Francois-Xavier Simon, BASF, Germany

Rheological Tools for the Emulsion Formulator

- Describing emulsions rheologically: Critical properties.
- Practical rheological tools for stability profiling approaches:
 - Predicting stability
 - Assessing instability as it proceeds
- Using rheology profiling for benchmarking sensory properties and spreading characteristics
- Tribometry: Another tool in the formulator's arsenal
- Neil Cunningham, Centre for Industrial Rheology, United Kingdom

Confocal Raman microscopy for characterization of semisolid preparations

- Principle of confocal Raman microscopy/microspectroscopy
- Characterization of inner structure of semisolids
 - Compatibility testing of excipients
 - Applications in stability testing
- Characterization of skin penetration

Dominique Lunter, University of Tübingen, Germany

Speakers

Neil Cunningham, Centre f. Industrial Rheology

Neil Cunningham is the founder and director of the Centre for Industrial Rheology (www.rheologylab. com). Neil started his career in rheology in 1995 as a sales engineer for TA Instruments in the



United Kingdom and Rheometric Scientific throughout the UK and Europe. Since becoming an independent consultant in 1998, Neil has consulted for many hundreds of companies worldwide and has trained an estimated three thousand formulators, researchers, process designers, and quality controllers in the principles and practical application of rheology and viscosity testing. Over that time he has gained an intimate knowledge of rheometry and viscometry and has gained a unique breadth of understanding of the needs of industries from pharmaceuticals and consumer healthcare products, to foods, cosmetics, and industrial coatings and adhesives.

Andreas Fisch, Novartis

Dr. Andreas Fisch is working since 2007 at Novartis Pharma in Basel, Switzerland as project leader in technical R&D of parenteral dosage forms. In addition, he is Technology Platform Leader of Parenteral Special Delivery Systems including



After a two years research fellowship at the Biomedical Research Center of Baxter Bioscience in Vienna, Austria, from 1997-2007 he led the Swiss Pharmaceutical Development Center of B.Braun Melsungen AG in Sankt Gallen and Crissier, focusing on parenteral colloids for plasma volume replacement.

Dr. Fisch obtained his PhD in pharmaceutical sciences on MHCclass II restricted antigen presentation at the Johannes-Gutenberg University in Mainz, Germany.

Michael Herbig, RaDes GmbH

Michael Herbig is co-founder and CEO of RaDes GmbH, Hamburg, a CRO with leading expertise in the development of liquid and semi-solid formulations. Michael holds a PhD in "Drug



Delivery and Formulation" from ETH Zurich, Switzerland and an MBA from OUBS, UK. He held positions of increasing responsibility in formulation development at Novartis, Basel and was Head of Pharmaceutical Development at Almirall Hermal, Reinbek, before starting RaDes in 2018. In particular, he focussed on expanding the understanding semi-solid dosage forms with regards to distribution processes and underlying thermodynamic principles in order to allow for a science-based, rational design. He is author of several publications peer reviewed journals and of three granted patent families.

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Speakers



Sandra Klein, University of Greifswald

Prof. Dr. Sandra Klein studied Pharmaceutical Sciences at the University of Frankfurt, Germany and graduated in 2000. At the same university she started her a graduate studies at the Institute of

Pharmaceutical Technology, where she has worked on developing biorelevant dissolution methods for oral modified release formulations under the supervision of Jennifer Dressman. She got her PhD in 2005 and was then a postdoctoral fellow at Eastman Chemical Company in Kingsport/TN, USA where she has started to work on enhancing the bioavailability of poorly soluble drugs with different polymer- and cyclodextrin-based approaches. From 2006 till 2010 Sandra Klein was a senior research associate at the Institute of Pharmaceutical Technology at the University of Frankfurt. Since 2010 she is Professor of Pharmaceutical Technology at the University of Greifswald, Germany. Her current research is focused on developing biorelevant dissolution methods for special patient groups, particularly the pediatric and geriatric population. Other research interests include the design of predictive and accelerated test methods for vaginal delivery systems and depot parenterals and enhancing the bioavailability of poorly soluble compounds. Sandra Klein is an APV member since 2000 and member of the American Association of Pharmaceutical Scientists (AAPS), the Controlled Release Society (CRS) and the European Paediatric Formulation Initiative(EuPFI) amongst others.



Delphine Marchaud, Gattefossé

Delphine graduated in 1996 from the School of Applied Sciences in Physicochemistry, Montpellier, France and completed her training with a Master 2 in Pharmaceutical Technologies. She began her

career at Sanofi initially in France and later in the USA, where she worked on the development of dosage forms with new chemical entities. In 1998, she joined Gattefossé at the headquarters in St Priest, France managing the Pharmaceutical Application Laboratory. From 2006 she took the lead of the Pharmaceutical Technical Division, with a team of scientists developing lipid based drug delivery platforms and novel applications. During this period she launched Gattefossé's formulation educational courses known as 'Lipid Schools' designed for pharmaceutical scientists and provided formulation assistance to customers. Delphine has authored numerous publications and she is an invited lecturer at business and academic seminars. Since January 2014, she is Director of the Marketing & Innovation department for pharmaceuticals at Gattefossé, piloting the marketing strategic group and the application laboratory group.

Francois-Xavier Simon, BASF

François-Xavier studied chemistry at the University of Metz (France) and achieved a doctorate in Chemistry and Physico-Chemistry of selfassembled 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.

Marc Willuhn, Willuhn Consulting AB

Marc Willuhn was VP R&D at Fresenius Kabi from 2014 until 2018 and led the Innovation & Development Centre in Uppsala, Sweden. In this role, he was responsible for pharmaceutical



development of parenteral nutrition products and successfully contributed to several approvals and launches.

Previously, he was Director Process Development at Baxter Healthcare in charge of pilot plant operations and tech transfers for parenteral products. Earlier in his career, Dr Willuhn worked in chemical development at Schering AG and Sigma-Aldrich.

Dr Willuhn obtained his PhD in organic chemistry at the Max Planck Institute for Coal Research and carried out post-doctoral research at the Faculté de Pharmacie in Paris, France.

Registration by fax +49 6131 97 69 69 or by email apv@apv-mainz.de



Location		Registration fee		Registration	Hotelreservation
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1dx 0049 211 20541 899		Coffee breaks, luncheon, electronic proceedings inc	dinner and luded.		Participants should make their own hotel reservation referring to the APV seminar
Date Course no.: 6767 from 01 April 2019	13:00 h 16:30 h	* Limited places for full time students available; written evidence must be submitted.			Deadline for special conference rate: 01 March 2019. Special rate: Single room incl. breakfast from 129,00 € per night
to 02 April 2019					Mainz, October 2018

Title, first name, last name *

APV Expert Workshop: Emulsions, 01 - 02 April 2019, Düsseldorf, Course no. 6767

Registration

As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation

After your registration was successfully processed, you will receive a confirmation.

Before the event

A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event

You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up

After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

Declaration of consent in respect of data protection

By registering for this seminar, I agree that the APV uses my data for the purpose of
processing the order and provides me with all relevant information.

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