the future of excipients is in our hands

Seminar: **APV/IPEC Europe Excipient Conference 2018**
- An update on regulatory developments and their application -
Course-No. **3190 from 18 to 19 September 2018, Lindner Hotel City Plaza, Cologne, Germany**
Course Leader: **Dr. Frank Milek, Vice-Chair to IPEC Europe; Aug. Hedinger GmbH & Co. KG**
Dr. Mahmud Yunis, IPEC Europe Board Member; Biogrund GmbH, Germany

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Programme

Tuesday, 18 September 2018 09:00-17:45 h

08:30-09:00 h Registration

09:00-10:30 h Three parallel workshop sessions:

WORKSHOPS: Achieving compliance for Excipients using IPEC Guidelines
"How it works in practice" (Workshops 1-3 will run in parallel two times)

Workshop 1:
How to implement appropriate GMPs in an excipients manufacturing site
– "What brings you from ISO 9001 to "Excipient GMP"
- What EXCiPACT requires above ISO 9001
- Development of a gap analysis and action plan
- Ongoing activities in the GMP compliant quality management system
- Maximising the benefits of EXCiPACT Certification

Dr. Iain Moore, Croda Europe Ltd., United Kingdom

Workshop 2:
Using IPEC Guidelines to streamline the audit process and simplify supplier oversight
– "Audit Preparation & Supplier Performance Evaluation: a win-win partnership"
- Real and perceived roles of the supplier and the customer during audits and quality performance review
- Practical approaches using IPEC Guides and documents when preparing for audits and evaluating performance
- The role of excipient GMP certification schemes in evaluating supplier compliance and performance
- Trends seen by workshop participants and potential new directions for IPEC guidance

Jeffrey Brambora, Novartis, Switzerland

Workshop 3:
Analytical data and COAs of suppliers
– "How to enable pharma industry to outsource excipient testing to suppliers"
- Regulatory requirements
- Expectations of pharma industry
- Realities in chemical industry laboratories
- IPEC and WHO COA Guidelines

Dr. Frank Milek, Hedinger, Germany

10:30-11:00 h Coffee break and table top exhibition

11:00-12:30 h
Repetition of workshop sessions 1-3 (Workshops 1-3 will run in parallel two times)

12:30-13:30 h Lunch break and table top exhibition

13:30-13:45 h
Review of workshops and opening of the conference
Dr. Frank Milek, Head of GMP and SHEQ Operations, Aug. Hedinger GmbH & Co. KG, Germany
Dr. Mahmud Yunis, Technical Director; Biogrund GmbH, Germany

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IPEC EUROPE APV

IPEC Federation presents: How Pharmacopoeias move to the future

13:45 h-14:00 h
Introduction of IPEC Federation
Dr. Frank Milek, Hedinger, Germany

14:00-14:45 h
The European Pharmacopoeia's General Methods Modernisation Program
- Background and objective
- Achievements to date
- Current challenges

Anne Garnier-Poidevin, EDQM, France

14:45-15:45 h
USP Focus on Excipients – Strategies and Opportunities for Excipient Standard Setting
- Update on USP's progress in updating excipients standards to help improve quality control testing
- Overview and updates on the challenges with setting specifications for pharmaceutical excipients composition and impurities.
- Overview and updates on USP's General Chapter <1059> EXCIPIENT PERFORMANCE, which provides information about which properties and test methods that might be important for a particular material in a particular application.
- Updates on USP's formation of several Joint Subcommittees (JSCs), including the development of an information chapter on co-processed excipients.
- Share progress on USP's engagement with stakeholders, including FDA, to explore paths for introduction of novel excipients into the development of pharmaceutical drugs

Catherine M. Sheehan, M.S., M.S. United States Pharmacopeia, United States of America
John A. Giannone; United States Pharmacopeia, United States of America

15:45-16:15 h Coffee break and table top exhibition

Hot topics in excipients regulatory compliance

16:15-17:00 h
Particulate matter in pharmaceutical starting materials and drug products – prevention and control
- Types, concerns and regulatory expectations
- Particle prevention and control
- IPEC-Americas Guide on Technically Unavoidable Particle Profile
- A practical approach of establishment of a TUPP and its

Dr. Thilo Jahr, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

17:00-17:45 h
Regulatory and safety challenges for excipients in parenteral formulations
- *How Inactive is an Excipient?*
- *Pharmaceutical and Safety Excipient Assessments*
- *Main Regulatory and Safety Challenges*
- *Systemic Toxicity, Local Tolerance and Immunological Safety*
- *Optimal Use of Online Databases*
- *Evaluation of Drug Product Appropriatene*

Dr. Dieter Röthlisberger, Lonza, Switzerland

18:30 h Social programme:
Meeting point at the hotel lobby: 18:25 h
Guided City tour by foot
Dinner: 20:00 h at H&A Tagesbar

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iPEC EUROPE

APV

Wednesday, 19 September 2018 09:00-16:30 h

09:00-09:45 h
Impact of excipients on oral drug bioavailability

- What are the main determinants of oral drug absorption?
- How can excipients affect oral bioavailability (BA)?
  - Intended and unintended excipient effects
  - Impact of excipient variability of oral BA
- How can excipients be used to control oral BA?
  - Controlled release formulations
  - Enhancing solubility and dissolution rate
  - Enhancing intestinal permeability?

Prof. Dr. Sandra Klein, University of Greifswald, Germany

09:45-10:30 h
Practical Approaches to Designing Lipid Based Drug Delivery Systems

- Introduction to Lipid-Based Excipients and Drug Delivery Systems
- Selection Criteria for Excipient use in Complex, Multi-Phase Formulations
  - Considerations of Excipient Complexity and Variability on Formulations
  - Effects of Ingredients on Performance and Bioavailability

Dr. Frank Romanski, BASF SE – Pharma Solutions, Germany

10:30-11:00 h Coffee break and table top exhibition

11:00-11:45 h
Solid dispersion formulations for small molecules:
The impact of excipients on bioavailability of poorly soluble drugs

- How can excipients affect oral bioavailability?
- How can excipients affect long-term stability?
- Screening methods to evaluate different excipients
- The role of excipients in solid dispersions
- Short overview of most common techniques to prepare solid dispersions

Dr. Thomas Quinten, The Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium

11:45-12:30 h
Excipients in Biopharmaceutical Formulations
– Identification and Classification Based on Molecular Interactions

- Role of Excipients and importance in biologics formulation development
- Characterization and choice of excipient candidates
- Molecular interactions and aggregation propensity of protein/antibody

Dr.-Ing. Christoph Brandenbusch, Technische Universität Dortmund, Germany

12:30-13:30 h Lunch break and table top exhibition

13:30-14:15 h
Applied rheological characterization of cellulose ether:
Thermo – sensitive performance related to controlled release applications

- The formation of a gel layer is of key importance for the controlled release (CR) performance of matrix tablets
- MethocelTM solutions show gel formation with increasing temperature and the relevance of these gel formati on to the CR performance is evaluated
- New rheological analysis techniques will be introduced in order to predict the CR performance of various MethocelTM grades

Dr. Matthias Knarr, Dow Food & Pharma Solutions, Germany

PTO

14:15-15:00 h
Personalized medicines by inkjet printing – the role of excipients

- Excipients in ink formulation (solvents, viscosity modifiers, nanocarriers, cyclodextrins)
- Materials in carrier substrates
- Excipients for controlling the drug release

Dr. Mirja Palo, Abo Akademi University, Finland

15:00-15:30 h Coffee break and table top exhibition

15:30-16:15 h
A Systematic Approach for Defining Key Excipient Attributes for Continuous Feeding

- Current state of the art
  - Manufacturability Classification System (MCS)
  - Database-based approaches for key material attribute definition
- A systematic approach by comparison of excipients in batch and continuous processes
  - Failure modes of excipients in batch vs continuous processing
  - Differences in terms of relevant/critical material attributes
- Advanced material characterization methodology with regard to continuous processing
  - Emerging key material attributes
  - Process characterization and modelling approaches
  - How to tackle excipient variability?
  - Case study: A systematic investigation of the impact of excipient material attribute on continuous feeding
- Conclusion: What should the “perfect” continuous manufacturing excipient look like?

Dr. Eva Faulhammer, RCPE, Austria

16:15-16:30 h
Closing remarks

****Programme is subject to change****