APV/IPEC Europe Excipient Conference 2018

– An update on regulatory developments and their application –

18 - 19 September 2018

Cologne · Germany

Course No. 3190

the future of excipients is in our hands

IPEC EUROPE

WORKSHOPS:
Achieving compliance for Excipients using IPEC Guidelines

How to implement appropriate GMPs in an excipients manufacturing site – "What brings you from ISO 9001 to Excipient GMP"

Using IPEC Guidelines to streamline the audit process and simplify supplier oversight – "Audit Preparation & Supplier Performance Evaluation: a win-win partnership"

Analytical data and COAs of suppliers – "How to enable pharma industry to outsource excipient testing to suppliers"

Fischmarkt © KölnTourismus GmbH, photograph by Jens Korte


Rheinauhafen © KölnTourismus GmbH, photograph by Dieter Jacobi

APV

Kölner Lichter © KölnTourismus GmbH, photograph by Dieter Jacobi

APV/IPEC Europe Excipient Conference 2018

the future of excipients is in our hands

IPEC EUROPE

APV

Dear Colleagues,

IPEC Europe and APV are delighted to invite you to our 7th annual conference on pharmaceutical excipients.

The conference will focus on "hot topics" in the area of excipient regulation and technology.

As part of the programme we will offer three parallel workshops to provide practical, hands-on insight and discussion on regulatory topics, with a view to IPEC Guidelines providing tools to achieve compliance. These workshops will focus on implementation of GMP in an excipient manufacturing site, supplier qualification and auditing, as well as analytical data and certificates of analysis provided by suppliers of excipients.

Beyond that the regulatory session will highlight compendial topics of EDQM and USP. Challenges relating to the control of particulate contamination in excipients and requirements for excipients in parenteral applications will be presented and discussed by pharma industry experts.

The technical and scientific part of the conference will deal with the importance of excipient on drug bioavailability. Low bioavailability is most common with oral dosage forms of poorly water-soluble, slowly absorbed drugs. Lipid based drug delivery systems will be presented as they can be an approach to overcome low bioavailability.

The design of drug release from modified-release (MR) dosage forms is intentionally different from that of an immediate-release drug formulation to produce a desired therapeutic purpose or improved patient compliance. Here we will discuss a method to predict the modified release performance of drugs.

Molecules used as active drug substances can be categorised into two classes – small and large molecules. Small, chemically synthesised molecules are the conventional active substances and still constitute over 90 percent of the drugs available on the market today. Contrary to small molecules, large molecules are complex and often consist of heterogeneous mixtures; they are becoming increasingly important. We will highlight the role of excipients in small/large molecule drug formulation.

New scientific findings in the molecular processes of life are advancing our knowledge of health and disease. The objective of individualised medicine is to make such knowledge useful for individually tailored prevention, diagnosis and treatment. As new drugs are elaborated that have differential effects within populations, there is also a need to consider new manufacturing methods. The requirements of excipients for individualised medicines and continuous manufacturing processes will be pointed out.

Last but not least networking and exchange of information is a key feature of the event and table-top exhibitions aligned to the conference will encourage communication between suppliers and users.

We are looking forward to welcoming you in Cologne.

Dr. Frank Milek
Vice-Chair IPEC Europe

Dr. Mahmud Yunis
IPEC Europe Board Member

Objectives

This event is designed to highlight current hot topics in the field of pharmaceutical excipients:

- Implementation of GMP in an excipient manufacturing site
- Qualification and auditing of suppliers
- Analytical data and certificates of analysis for excipients
- The European Pharmacopoeia's General Methods Modernisation Programme
- USP – Strategies and Opportunities for Excipient Standard Setting
- Particulate matter in pharmaceutical starting materials and drug products
- Regulatory and technical challenges for excipients in parenteral formulations
- Formulation topics
  - Impact of excipients on oral drug bioavailability
  - Lipid-based drug delivery systems (to overcome poor API solubility/bioavailability)
  - Analysing Thermo-Sensitive Properties of HPMC to predict Modified-Release Performance
  - Small molecules: The Effect of excipients on small molecules
  - Large molecules: Thermodynamic approach to explore excipient-mixture and novel excipients in high concentration protein formulations
  - Individualised medicines - the role of excipients
  - Continuous Manufacturing: A systematic Approach for defining Key Excipient Attributes for Continuous Feeding

Target Group

This conference is intended for professionals working in:

- Development, manufacture and quality
- Distribution and sales
- Qualification of suppliers
- Application and control of pharmaceutical excipients for medicinal products.

The seminar is also intended for members of regulatory authorities and purchasing departments.

Programme Committee

Amina Faham
IPEC Europe Board Member
Dow Chemical, Switzerland

Hubertus Folttmann
Member of APV
BASF SE, Germany

Frank Milek
Vice-Chair IPEC Europe
Aug. Hedinger GmbH & Co. KG, Germany

Mahmud Yunis
IPEC Europe Board Member
Biogrund GmbH, Germany

Programme

Tuesday, 18 September 2018 08:30 to 18:00 h

Registration

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

Coffee Break and Table Top Exhibition

Repetition of Workshops 1-3
(Workshops 1-3 will run in parallel)

Review of workshops

APV/IPEC Europe Excipient Conference 2018

Programme

Opening of Conference
Dr. Frank Milek, Hedinger & Dr. Mahmud Yunis, BIOGRUND

IPEC Federation presents:
How Pharmacopoeias move to the future

Introduction of IPEC Federation
Dr. Frank Milek, Hedinger, Germany

The European Pharmacopoeia's General Methods Modernisation Program
- Background and objective
- Achievements to date
- Current challenges

Anne Garnier-Poidevin, EDQM, France

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. & John A. Giannone
United States Pharmacopeia, United States of America

Coffee Break and Table Top Exhibition

Hot topics in excipients regulatory compliance

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 benefit to the pharmaceutical industry

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

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 Appropriateness

Dr. Dieter Röthlisberger, Lonza Ltd, Switzerland

Wednesday, 19 September 2018 08:30 to 16:30 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

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

Coffee Break and Table Top Exhibition

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

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

Lunch Break and Table Top Exhibition

Social programme
We are delighted to invite you to join us for dinner and a sightseeing tour.
Come and meet colleagues and specialists in the field of excipients around the world in an enjoyable and relaxed atmosphere.

Rheinpanorama© KölnTourismus GmbH, photograph by Dieter Jacobi

Programme

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

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

Coffee Break and Table Top Exhibition

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

Closing remarks

Programme is subject to change

Table Top Exhibition/Sponsoring

As well as in the last years, we are offering you the opportunity to present your company, products and services to a truly focused target market. Here you can reach everyone dealing with excipients without wastage.

We are offering a tabletop for 995 Euro (excl. VAT) + one mandatory full conference registration.

Space is limited, and applications will be dealt with on a "first come, first served" basis.

A tabletop includes:

- one table
- two chairs
- electricity
- power supplies

For detailed information about exhibiting and the different sponsoring options, please go to our website **www.apv-mainz.de** or contact Antonia Herbert, **ah@apv-mainz.de**.

Floorplan

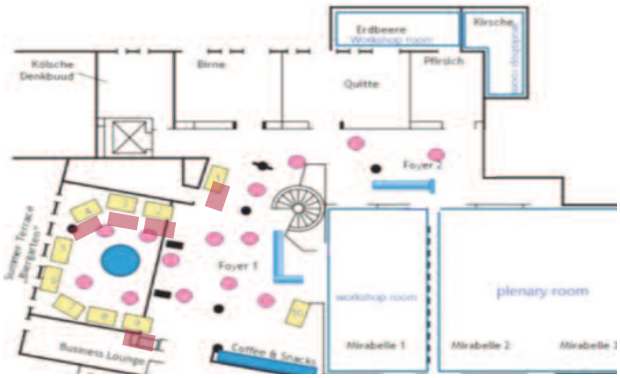

Table 1 Excipia.
Table 2 BASF
Table 3 BRENNTAG
Table 4 GRANU TOOLS
Table 9 HEDINGER

The exhibition and the attractive social programme provides the participants an opportunity to meet up with the other visitors

Sponsoring Options

For this event we offer different sponsoring packages for you. If you are interested in other sponsoring options not listed, please get in touch with us and we will find a way to integrate your sponsoring idea.

Sponsoring options are for example:

- USB sticks
- Meeting bags sponsored by BIOGRUND
- Lanyards sponsored by Qualicaps
- Insert in bags
- Social programme
- Coffee breaks

APV/IPEC Europe Excipient Conference 2018

Speaker

Jeffrey Brambora
Novartis Pharma AG, Switzerland

After studying organic and biochemistry in the United States, Jeffrey Brambora started his pharmaceutical career with Eli Lilly as a manufacturing chemist and later also held roles in multiple QA functions. Now with Novartis Pharma and based in Basel, Switzerland, Jeffrey has almost two decades of international experience working for multi-national pharmaceutical companies in quality management systems, supply chain quality management, and manufacturing quality. He has audited against a wide range of quality standards in industries as diverse as commodity and fine chemicals, API, excipients, anti-counterfeiting technologies, primary and secondary packaging materials, drug product manufacturing and packaging operations, and warehousing and distribution. Jeffrey has authored multiple internal manuals, guidelines, procedures, and training courses. He was also a contributor to PS 9000, the pharmaceutical GMP standard for printed packaging materials, and was a co-author of NSF/IPEC/ANSI 363, the United States national standard for excipient GMP, and the EXCiPACT™ GMP Annex. He is sought out as a mentor to new as well as experienced auditors and is certified by the American Society for Quality as a Pharmaceutical GMP Professional (CPGP) and Quality Auditor (CQA).

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

Dr. Christoph Brandenbusch studied Chemical Engineering at the Department of Biochemical and Chemical Engineering at TU Dortmund, (Germany) 2003-2007. He finished his Ph.D. thesis in the field of downstream processing in biocatalysis in 2011. Since 2012 he works as a group leader at the Laboratory of Thermodynamics, Department of Biochemical and Chemical Engineering, TU Dortmund (Germany). His main research fields include: Novel strategies for protein purifications in pharmaceutical bio-processes (e.g. precipitation, aqueous two-phase extraction) including hybrid-modeling approaches therefor. The development of physical-sound models for the identification of excipients and excipient mixtures in high-concentration biopharmaceutical formulations.

Dr. Eva Faulhammer
RCPE, Austria

Eva Faulhammer held her diploma in Pharmacy and Masters in Chemical and Pharmaceutical Engineering and now is a senior scientist at RCPE. Her PhD research was in the field of Quality by Design driven process development and optimization for a low-dose capsule filling process using advanced material characterization and statistical methods. Afterwards she was working in powder processing and process optimization for oral solid dosage forms and inhalation application. Currently her research focus is powder technology and advanced material science with respect to continuous manufacturing of solid dosage forms.

Anne Garnier-Poidevin
EDQM, France

Anne Garnier-Poidevin graduated in Pharmacy in 2005 from the University of Strasbourg and she obtained a Master's degree in European Community Law and Pharmaceutical Regulation in 2006.
She joined the European Phamacopoeia department of the European Directorate for the Quality of Medicines & HealthCare (EDQM) in 2005, where she is currently scientific program manager in charge of group of experts 13H (Fatty oils and derivatives, polymers). From 2005 to 2015, she was involved in the Expert Group dealing with Chemicals groups of Experts.

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

Dr. Thilo Jahr studied Chemistry at the Universities of Mainz and Toronto and holds a PhD in Physical Chemistry. In 2002 he started his career in the pharmaceutical industry in a development unit of Boehringer Ingelheim Pharma GmbH & Co. KG. In the past 16 years Thilo held various positions in development, operations and contract manufacturing management with a focus on pharmaceutical technology of solid dosage forms as well as dry powder inhalers.
Since 2017 he leads a team of process technology experts supporting the solids production in Ingelheim with respect to process and transport validation, troubleshooting and various transfer projects.
Since 2013 Thilo is participating in internal as well as external working groups on the topic of how to handle particulate matter in pharmaceutical products.

John Giannone
United States Pharmacopeia, USA

John Giannone is Senior Director of Strategic Marketing and Program Operations for Excipients at US Pharmacopeial Convention (USP). Mr. Giannone joined USP in June of 2016 with over 15 years of experience in the Pharmaceutical Excipients business, including serving as Chairman of IPEC Americas, and is responsible for commercial activities at USP related to Excipients.
Beyond Excipients, John has more than 35 years of chemical industry experience including Research and Development, Supply Chain, Marketing, Sales/Sales Management and Business Management.

Prof. Dr. Sandra Klein
University of Greifswald, Germany

Sandra Klein is currently a Professor of Pharmaceutical Technology at the Ernst-Moritz-Arndt-University in Greifswald, Germany. She got her pharmacist's license and her Ph.D. from the Goethe University of Frankfurt and was a postdoctoral fellow at Eastman Chemical Company in Kingsport/TN, USA. She has more than 15 years of experience in the development of biorelevant in vitro models for predicting in vivo drug release and absorption and is (co-) author of various original manuscripts and book chapters on this topic. Her current research is focused on developing biorelevant dissolution methods for special patient groups, particularly the pediatric and geriatric population, the design of predictive and accelerated test methods for lozenges, vaginal delivery systems and depot parenterals and on enhancing the bioavailability of poorly soluble compounds. Beside her research and teaching activities Sandra Klein is a member of AAPS, CRS and DPhG, a member of the APV board, a core group member of EuPFI and editor-in-chief of DiePharmazie, an international pharmaceutical journal.

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

Dr. Matthias Knarr studied chemistry at the University of Hamburg and holds a Ph.D from the Institute for Technical & Macromolecular Chemisty. He has been working for Dow since 2005 at the Bomlitz R&D Center in Germany. Matthias Knarr leads the lab for pressurized synthesis of new cellulose ethers as well as the labs for the applied material characteristics. His main focus is the development of new cellulose ether products according to the specific market needs and to tailor their performance based on structure property relationships. Additionally he is certified Six Sigma Black Belt.
Matthias Knarr authored 10 journal publication in e.g. Carbohydrate Polymers, Food Hydrocolloids or Macromolecular Symposium; (co-) authored / presented more than 50 presentations on international events and holds more than 32 US / EP or JP granted patents.

Speaker

Dr. Frank Milek
Hedinger, Germany

Dr. Frank Milek is an industrial pharmacist. He is PhD pharmacist graduated at the Universities of Würzburg and Tübingen (Germany). He is working for more than 20 years in pharmaceutical excipient industries, especially in the field of supply chain, distribution and manufacture. Frank is an expert for regulatory affairs, quality system standards and GMP/GDP compliance. He is a registered Qualified Person according to EU regulation and responsible at Aug. Hedinger GmbH & Co. KG, a specialised excipient supplier in Germany, for Quality, RA and GMPs.
Frank Milek is member of different committees of industrial trade associations (FECC, IPEC, BAH and APV). He is currently chairman of the Good Trade and Distribution Practice Committee of the European Association of Chemical Distributors (FECC) and vice-chair of the International Pharmaceutical Excipients Council Europe (IPEC Europe).

Dr. Iain Moore
Croda Europe Ltd., United Kingdom

Dr. Iain Moore is Global Head of Quality Assurance Croda Europe Ltd, a manufacturer of speciality and performance chemicals based in the United Kingdom. After completing his doctorate studies in organometallic chemistry he joined BP Chemicals to research and develop C1chemistry. Since moving to Croda in 1987, he has acted at the technical – customer interface, led a team of chemists in the development of Croda's products before holding various QA roles since 1995. This includes implementing Excipient and API GMP systems at two manufacturing sites, including two successful MHRA inspections. He is one of the co-authors of the PQG PS 9100:2002 guide for pharmaceutical excipients, the IPEC-PQG GMP Guide for Pharmaceutical Excipients and the EFfCI GMP Guide and standard 2012 for Cosmetic Ingredients. He is past chair of the IPEC Europe GMP Committee and is currently President of the Board of EXCIPACT asbl.

Dr. Mirja Palo
Abo Akademi University, Finland

Dr. Mirja Palo is post-doc researcher in Professor Niklas Sandler's group at Åbo Akademi University (Finland). She received her PhD in pharmaceutical sciences from Åbo Akademi University and the University of Tartu (Estonia). Her research interests are related to printing technology in pharmaceutics, individualized drug delivery systems, on-demand manufacturing and quality control.

Dr. Thomas Quinten
Janssen, Belgium

Thomas Quinten obtained a master degree in Pharmaceutical Sciences followed by a PhD in Pharmaceutical technology (2010) from the University of Ghent, with research focusing on injection moulding as a pharmaceutical production technology to develop sustained-release matrix tablets. After graduating, Thomas joined several companies and was responsible for the formulation and development of liquid, semi-solid and solid drug products. Thomas has been working for Johnson & Johnson in the Pharmaceutical Development and Manufacturing Sciences - Oral Solids Development group since 2015. In this role, he has been involved in early and late drug product development programs with focus on enabling technologies aiming to increase the bioavailability of poorly soluble drug compounds.

Dr. Dieter Röthlisberger
Lonza Ltd, Switzerland

Since June 2018 Dr. Dieter Röthlisberger holds the position of Head of Technical Project Leadership at Lonza Ltd, Drug Product Services in Basel, Switzerland.
He has 30 years pharmaceutical and industrial experience in different areas of formulation research and development, including formulation development of liquid and semi-liquid, sterile and oral dosage forms, for preclinical and clinical studies, clinical supply manufacturing of biopharmaceuticals, outsourcing management and development of parenteral dosage forms for pharmacokinetic and mass balance studies.
Since 10 years, he is also lecturer at the Master Course in Pharmaceutical Sciences given at the Swiss Federal Institute of Technology Zurich (ETHZ).

Dr. Frank Romanski
BASF SE – Pharma Solutions, Germany

Dr. Frank Romanski studied Chemical Engineering at Rutgers University located in the US, graduating with a Ph.D. in 2011. His core areas of technical expertise are focused on colloids, solubilization, surfactant physical chemistry and multi-phase systems. After holding a range of technical and commercial positions at BASF Corporation based in the US, he is currently on a delegation assignment as the Global Technical Marketing Manager at BASF SE based in Ludwigshafen, Germany. Today, he is responsible for the Solubilization, Softgel, and Biologics Technical Platforms, with specialization in the use of Oleochemicals and EO/PO Polymers.

Catherine M. Sheehan, M.S., M.S.
United States Pharmacopeia, USA

Ms. Sheehan is currently the Senior Director of Science – Excipients at the United States Pharmacopeia (USP), Rockville, MD. In her current role, she co-leads the Excipients Science Program Unit responsible for championing the development of global quality excipient standards and related programs, outreaching to stakeholders, partnering to improve awareness and advocating for adoption of new and up-to-date excipient quality standards and related programs. Responsibilities include, excipient standard setting activities supporting the USP Council of Experts, two Excipient Monograph Expert Committees and the General Chapters Expert Committees responsible for development and update of high priority excipient monographs and related general chapters as part of USPs Up-To-Date initiative. Her current responsibilities also include support of the Pharmacopeial Discussion Group (PDG) comprising the USP, European Pharmacopoeia and Japanese Pharmacopeia to successfully harmonize excipient monographs and related excipient chapters undergoing harmonization through PDG. She also supports other USP's collaborative efforts with pharmacopeial bodies outside PDG such as bi lateral harmonization of excipient monographs. Ms. Sheehan is active in AAPS and RAPS. Ms. Sheehan holds both an M.S. Regulatory Science degree and M.S. Molecular Biotechnology degree from The Johns Hopkins University, Baltimore, USA.

Dr. Mahmud Yunis
BIOGRUND, Germany

Dr. Mahmud Yunis has been working for 13 years at BIOGRUND in several positions.
In his current function as Technical Director, he is responsible for preparing and implementing global strategic regulatory plan for BIOGRUND products and the strategic development of the Quality, Production and R&D department. He has a PhD degree in Analytical Chemistry from University of Muenster, Germany. Before joining BIOGRUND he worked for a consulting company on the area of GxP procedures and processes for five years.

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the future of excipients is in our hands

IPEC EUROPE

Registration by fax +49 6131 9769-69

Location

Lindner Hotel City Plaza
Magnusstraße 20
50672 Köln, Germany
www.lindner.de/koeln-hotel-city-plaza

Date

Course No. 3190
from 18 Sept. 2018 08:30 h
to 19 Sept. 2018 16:30 h

Registration fee

Industry	1590 EUR
Academia/ Authorities	795 EUR

Plus VAT

Coffee breaks, lunch, dinner and proceedings included.

I herewith repealable authorise APV to use my E-mail address to send me APV relevant material including current programme information. My acceptance can be cancelled at any time in writing.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Hotel reservation

Lindner Hotel City Plaza
Magnusstraße 20
50672 Köln, Germany
www.lindner.de/koeln-hotel-city-plaza
Phone: + 49 221 2034 700
Mail: info.cityplaza@lindner.de
Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 06.08.2018
booking code: APV-IPEC
Special rate:
Single room incl. breakfast buffet from 119,- EUR per

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.

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Please select **2** of the following workshop sessions (please tick only 2)

- ☐ How to implement appropriate GMPs in an excipients manufacturing site
- ☐ Using IPEC Guidelines to streamline the audit process and simplify supplier oversight
- ☐ Analytical data and COAs of suppliers

Your registration fee also includes the participation in the Social Event.
Please let us know if you wish to attend:

- ☐ Yes
- ☐ No