

# 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"



# APV/IPEC Europe Excipient Conference 2018

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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 Foltmann**  
Member of APV  
BASF SE, Germany

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

**Mahmud Yunis**  
IPEC Europe Board Member  
Bioground 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

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## Programme

### Opening of Conference

*Dr. Frank Milek, Hedinger, Germany*

*Dr. Mahmud Yunis, BIOGRUND, Germany*

*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 (TUPP)
- A practical approach of establishment of a TUPP and its benefit to the pharmaceutical industry

*Dr. Malte Klemt, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*

#### Regulatory and safety challenges for excipients in parenteral formulations

*Dieter Röthlisberger, Lonza, 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.*



## 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
- Methocel™ solutions show gel formation with increasing temperature and the relevance of these gel formation to the CR performance is evaluated
- New rheological analysis techniques will be introduced in order to predict the CR performance of various Methocel™ 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](http://www.apv-mainz.de) or contact Antonia Herbert, [ah@apv-mainz.de](mailto:ah@apv-mainz.de).

## Floorplan



Table 1



Table 2



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
- Lanyards
- 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 Pharmacopoeia 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.



**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. Malte Klemt**  
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Dr. Malte Klemt studied Pharmacy in Mainz. He graduated as PhD in 2005 focusing on isolation, structure characterization and evaluation of genetic/molecular effects of marine natural products. He started his career in pharmaceutical industry in Quality Control of excipients, intermediates and drug products at Boehringer Ingelheim Pharma GmbH & Co. KG. After that he worked as a Process Engineer and as a Qualified Person for inhaled dosage forms. Since 2016, he is heading a QC unit that is responsible for launch & lifecycle management of pharmaceutical starting materials and medical devices.



**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 Chemistry. 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 C1 chemistry. 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**  
Åbo 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 pharmaceuticals, 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. 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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EUROPE



## Location

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

## Registration fee

**Early Bird Fee**  
*before 30 June 2018*  
Industry 1490 EUR  
Authorities 745 EUR  
Plus VAT

**Regular Fee**  
*after 30 June 2018*  
Industry 1590 EUR  
Authorities 795 EUR  
Plus VAT

## Date

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

Coffee breaks, lunch, dinner  
and proceedings included.

## 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.

Members of authorities pay half of the registration fee respectively.

## 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: 23.07.2018  
**booking code: APV-IPEC**  
Special rate:  
Single room incl. breakfast buffet from 119,- EUR per night.

### 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.

- pay via invoice
- pay via credit card (please fill in below)
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  - Visa
  - Mastercard

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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