IPEC Europe Excipient Conference

2022

– An update on regulatory developments and excipient applications in Drug Delivery –

10th ANNIVERSARY

27 - 28 September 2022

Frankfurt am Main ▪ Germany

Course No. 3255

incl. Workshops:

Data Integrity –
current experiences

Internal analytical method harmonisation –
an industry approach to safe testing resources

Managing appropriate transport conditions for
excipients – current situation and experiences

IPEC EUROPE 30 YRS APV

IPEC Europe Excipient Conference 2022

Dear Colleagues,

IPEC Europe and APV are delighted to invite you to our 10th annual conference on pharmaceutical excipients slated on 27-28 September 2022 in Frankfurt, Germany. We are also pleased to inform you that we will celebrate our 10th anniversary during our social program taking place on the evening of the first day.

The conference will be held on two days: from Tuesday (morning) until Wednesday (evening) and will focus on regulatory topics relating to pharmaceutical excipients and technology.

The day one will focus on regulatory topics and we will offer five presentations and three "workshops". The presentations will cover-current hot topics like IPEC-PQG GMP guide where you will learn the key changes, the structure and how best to implement. Other-critical topics such as new developments on excipients, microplastics and parenteral will also be covered.
The regulatory workshops aim to provide detailed practical information about current topics supporting industry to comply withregulatory requirements and other expectation. These "workshops" will be held two times in parallel to allow participants to attendtwo of the three sessions. These sessions will allow practical exercises and discussions related to the topics covered. Participants willhave the opportunity to exchanges their personal experience with colleagues out of the same industrial and regulatory environment.Topics will be data integrity, internal analytical method harmonisation and excipient transportation.

Since excipients are key parts of the formulation of medicines, we will open the second day with USP's Emerging/ Iterative approachto excipients standards development and its application to novel excipients. Afterwards we will take the opportunity to listen to theuse of 3D printing in drug delivery, biodegradable excipients in parenteral application and the latest advance in coating approachesfor gastro-intestinal dosage forms.
In recent years, large molecules research has been at the forefront of drug development, offering treatment options for many medicalconditions. Here we will present on permeation enhancer strategies for oral delivery and the Sa-RNA vaccines delivery options. Youwill also listen into functional characterisation of excipients, as there is a need in the pharma industry for an in-depth understandingof excipients roles in drug delivery applications especially for emerging trends in the design and development of drug products.

We are looking forward to welcoming you in Frankfurt, Germany.

Dr. Amina Faham
IPEC Europe Chair

Dr. Frank Milek
IPEC Europe Board Member

Dr. Mahmud Yunis
IPEC Europe Board Member

IPEC Europe Excipient Conference 2022

Objectives

The primary goal of the conference is to highlight current hot topics in the field of pharmaceutical excipients.
Take this opportunity to share your experiences and discuss with colleagues of pharmaceutical industry, academics, authorities as well as with manufacturer and distributors of pharmaceutical excipients.

This year again, you will be able to choose two out of three workshops on the first day:

- Data Integrity.
- Internal analytical method harmonisation.
- Managing appropriate transport conditions for excipients – current experiences.

Further hot topics of the conference in this year will be:

- The IPEC-PQG GMP Guide 2022: what's new and what's not.
- New developments on excipients at EDQM.
- Microplastics.
- Excipients for parenteral dosage forms.
- USP's Emerging/ Iterative Approach to Excipients Standards Development and its application to novel excipients.
- 3D printing in drug delivery: from prototyping to customized device designs.
- Biodegradable excipients for parenteral controlled release: concepts, performance and new applications.
- Tailored gastro-intestinal targeting- advanced coating approaches to meet industrial needs.
- Permeation enhancer strategies for oral delivery of large molecules.
- Delivery options for Sa-RNA vaccines.
- Functional characterization of excipients.

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

Dr. Amina Faham
IPEC Europe Board Member
International Flavors & Fragrances Inc. (IFF), Switzerland

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

Dr. Mahmud Yunis
IPEC Europe Board Member
BIOGRUND, Germany

Programme

On Monday, 26 September, at 19.00 h, participants are invited to a welcome reception at the Conference Hotel.

Tuesday, 27 September 2022 09:00 to 18:00 h

Registration 08:30 -09:00 h

Opening of Conference 09:00 h
Dr. Amina Faham, International Flavors & Fragrances Inc., Switzerland
Dr. Frank Milek, Aug. Hedinger GmbH & Co. KG, Germany
Dr. Mahmud Yunis, BIOGRUND, Germany

Introduction of IPEC Federation
Dr. Frank Milek, Aug. Hedinger GmbH & Co. KG, Germany

The IPEC-PQG GMP Guide 2022: what's new and what's not
This presentation will help attendees understand:

- key changes from the 2017 GMP Guide;
- the structure of the 2022 GMP Guide; and
- how to understand and implement the guidance given in the 2022 GMP Guide.

Jeffrey Brambora, Principal GMP Consultant, BlackTower Quality Group, Switzerland

New development on excipients at EDQM

- Update on the Ph. Eur. Strategy for excipients
  - ☐ Work programme for new and revised monographs
  - ☐ Focus for the coming years
- Pharmacopoeial harmonisation for excipients
- CEP for excipients, challenges and opportunities

Hélène Bruguera., Head of the CEP Department, EDQM, Council of Europe, France

Coffee Break and Table Top Exhibition

What Does the Proposed ECHA Microplastics Resolution Mean for Excipients & Pharmaceuticals?

- About the restriction
  - ☐ Background, Time schedule
  - ☐ Measures: Ban, Labelling, Reporting
  - ☐ Purpose of Labelling and Reporting
  - ☐ Practical examples
- 'How to Document' from IPEC Europe and IPEC Americas

Alberto Celada, International Flavors & Fragrances Inc., Switzerland

Excipients for parenteral dosage forms – from a Novo Nordisk perspective

- The regulatory framework and specific requirements for parenteral excipients
- Analytical aspects: Sampling, Compendial requirements, Authority expectations
- Requirements towards suppliers, including PDA report 54.5
- Facing the future: new digital solutions, direct supply

Lotte Kok, Novo Nordisk, Denmark

Lunch Break and Table Top Exhibition

IPEC Europe Excipient Conference 2022

Programme

Workshops:
(Workshops 1-3 will run in parallel two times)

Workshop 1
Data integrity – current experiences
- Data integrity requirements in the quality control laboratory
- Data governance/managing risks
- What pharm. manufacturers expect from their excipient suppliers
- Sharing and learning from each other
- Setup of a data integrity project
- Appropriate alternative controls for Data integrity

Dr. Bernhard Appel, Roche, Germany
Ann Gulau, International Flavors & Fragrances Inc., US

Workshop 2
Internal analytical method harmonisation – an industry approach to safe testing resources
- Pharmacopoeial review and harmonisation – Challenges for multicompendial compliance of excipients
- Strategy for multicompendial compliance – Internal analytical method harmonisation – an industry approach to safe testing resources?
- Practical approach – Example: Internal analytical method harmonisation for an excipient to minimize non value-added testing
- Discussion

Tanja Natterer, Aug. Hedinger GmbH & Co. KG, Germany

Workshop 3
Managing appropriate transport conditions for excipients – current situation and experiences
- IPEC Europe paper on the current situation
- Excipient Transport in IPEC Guides
- Discussion and exchange of experiences and opinions

Dr. Frank Milek, Aug. Hedinger GmbH & Co. KG, Germany

Coffee Break and Table Top Exhibition

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

Wednesday, 28 September 2022 09:00 to 16:30 h

USP's Emerging/ Iterative Approach to Excipients Standards Development and its application to novel excipients
- USP is fostering an integrated stakeholder engagement model to incorporate stakeholder inputs across stages of standard development from an early exploratory, to pre-compendial stage, to a compendial and post-publication stage.
- The iterative approaches are becoming increasingly important and introduces the concept of an "emerging standard" - a standard under development made available at an earlier stage for stakeholder input and contributions.
- The iterative approach and emerging standard become most critical when there is a strong need for a public standard in an evolving regulatory environment, such as for novel excipients.
- USP is seeking comments on the emerging standards concept and how best to advance its iterative approaches. USP looks forward to engaging with stakeholders to develop standards and help ensure the quality of excipients used in medicines.

Catherine Sheehan, DRSc., MS., MS., United States Pharmacopeia, US

3D PRINTING

3D printing in drug delivery: from prototyping to customized device designs
- Biodegradable 3D-printed biomedical devices
- Shape memory materials
- Non-vascular stents
- Peroral delivery of peptides

Prof. Dr. Jean-Christophe Leroux, ETH Zürich, Switzerland

Coffee Break and Table Top Exhibition

DRUG DELIVERY & EXCIPIENTS

Biodegradable excipients for parenteral controlled release: concepts, performance and new applications
- concept of parenteral controlled release
- material properties of relevant excipients
- material combinations and new applications

Prof. Dr. Karsten Mäder, Martin Luther University Halle-Wittenberg, Germany

Social programme

Join us for a fascinating tour with networking dinner. Come and meet colleagues and specialists in the field of excipients around the world in an enjoyable and relaxed atmosphere.

IPEC Europe Excipient Conference 2022

Programme

Tailored gastro-intestinal targeting- advanced coating approaches to meet industrial needs

- EUDRAGIT® - The functional flexibility to address specific API and therapy requirements
- EUDRACAP™ - Functional ready-to-fill capsules
- EUDRATEC® Fasteric - The effective targeting of the upper small intestine by combining enteric protection with rapid release at a defined pH from 3.0 to 5.5 or more

Felix Hofmann, Evonik Operations GmbH | Nutrition & Care, Germany

Lunch Break and Table Top Exhibition

Permeation enhancer strategies for oral delivery of large molecules

- Why are permeation enhancers used to orally deliver large molecules?
- Permeation enhancer strategies included on marketed products and clinical trials
- What is their mechanism of action?

Kelly-Kalliopi Vanderas, Hoffman La Roche, Switzerland

VACCINES & EXCIPIENTS

Lipid Excipients in mRNA delivery (tbc.)

- role of lipid excipients in mRNA formulations
- regulatory background and requirements for lipid excipients
- experience and challenges with submission of lipid excipient data in Market Authorisation Applications

Dr. Lars Albermann, Merck KGaA, Germany

Coffee Break and Table Top Exhibition

CHARACTERIZATION OF EXCIPIENTS

Functional characterization of excipients – a case for UV–vis imaging

- Whole-dosage form UV–vis imaging a potential tool for characterization of excipients used in solid oral dosage forms
- Monitoring swelling and erosion processes
- Imaging drug – excipient interactions

Professor, Ph.D. Jesper Østergaard, University of Copenhagen, Denmark

Closing remarks

Programme is subject to change

Table Top Exhibition

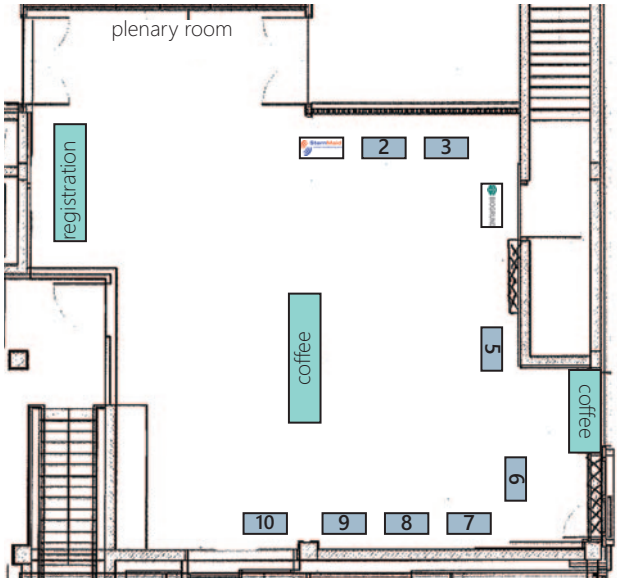
As well as in the last years, we are offering you the opportunity to present your company, products and services to a truly focused target market. Here you can reach everyone dealing with excipients without wastage.

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



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 *-booked-*
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- Insert in bags
- Social programme
- Coffee breaks

For detailed information about exhibiting and the different sponsoring options, please go to our website www.apv-mainz.de or contact Katrin Kälkert, kk@apv-mainz.de.

IPEC Europe Excipient Conference 2022

Speaker

Lars Albermann
Merck KGaA, Germany

Lars Albermann, Head of Pharma Registration and Regulatory Projects, Merck KGaA.
Originally a molecular biologist, for the last 14 years Lars Albermann has been working in several regulatory positions in pharmaceutical industry as well as contributing to a number of industry associations.
Currently, he is responsible for a team of regulatory experts in Merck Life Science Regulatory Management working on regulatory topics mainly related to APIs and excipients.

Dr. Bernhard Appel
Roche Diagnostics GmbH, Germany

Dr. Bernhard Appel is pharmacist in the QA department for pharmaceutical production at Roche Diagnostics GmbH Mannheim. He has been working in the field of computer system validation since his entry into the pharmaceutical industry.

Jeffrey Brambora
BlackTower Quality Group, Switzerland

After studying organic and biochemistry in the United States, Jeffrey Brambora started his pharmaceutical career with Eli Lilly as a manufacturing chemist, later holding multiple roles in QA, including Consultant Supplier Quality Auditor. After moving to Europe, he worked as a Senior GMP Auditor for Novartis Pharma in Basel, Switzerland. Jeffrey has more than 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 a wide range of industries and is certified by the American Society for Quality as both a Quality Auditor (CQA) and a Pharmaceutical GMP Professional (CPGP). Jeffrey has co-authored multiple international GMP guidelines and standards, including NSF/IPEC/ANSI 363 (the United States national standard for excipient GMP), the EXCiPACT® GMP Annex, and the latest version of the IPEC-PQG GMP Guide, which is the subject of his presentation. In his auditing and consulting work today, Jeffrey concentrates primarily on lead auditor training and quality management system optimization.

Hélène Bruguera
EDQM, France

Ms Hélène Bruguera graduated in Biochemistry from the University of Nancy, France and has a Master in Industrial Pharmacy from the University of Strasbourg, France.
She worked for the pharmaceutical industry for 10 years in analytical development and in the preparation of the quality part for marketing applications.
She joined the EDQM in year 2000, and is currently the Head of the Certification Department. She deals with the management of CEP applications as well as the EDQM inspection programme for active substances manufacturers. She is also involved in international platforms related to the quality of medicines and active pharmaceutical ingredients (ICH, IPRP), and is currently co-chair of the IPRP Quality Working Group (QWG).

Alberto Celada
International Flavors & Fragrances Inc., Switzerland

Alberto Celada is currently Regulatory Affairs Manager for theEMEA Pharma Solutions business product portfolio of InternationalFlavors & Fragrances (IFF). He is an active participant in IPEC Europe, is theVice-President of the International Cellulosics Association (ICA) and representsIFF in various industry groups and trade associations for APIs and food additives. Alberto joined the Dow Chemical Company in 2015, which Dow Pharma &Food Solutions business unit later became part of DuPont and then of IFF.Alberto holds a M.Sc. degree in Chemistry from the University of Fribourg andETH Zürich, as well as a M.A. degree in Business Management from the University of Fribourg and HSG St. Gallen, Switzerland. Prior to working in regulatoryaffairs, Alberto was part of the medical device company Edwards Lifesciences'marketing department.

Dr. Amina Faham, IPEC Europe Board Member
International Flavors & Fragrances Inc., Switzerland

Amina earned a Ph.D. degree in Pharmaceutical Sciences from school of Pharmacy, University de la Mediterranean France. Amina has over 15 years of Pharmaceutical industry experience in oral solid dosage forms with emphasis on modified drug release technologies, process development and optimization, and project management with companies including Ethypharm, Pfizer Pharmaceuticals and Colorcon, all based in North America region. Amina has a strong background and experience of fundamental areas which apply to product drug delivery, risk management, control strategy and market analysis. She has strong knowledge on regulatory affairs support of submissions and on-going regulatory compliance processes. She joined The Dow Chemical Company in 2011 as a pharma application specialist to support the business growth in Europe Middle East and Africa, and moved with her family to Switzerland. Between 2013 and 2017, Amina occupied several leadership responsibilities roles within R&D organization. As a result of the Dow DuPont merger, Amina is leading the global application development and innovation of combined heritages FMC and Dow businesses since 2018. Her main responsibilities is to build, develop and lead high performing global team for high impact on business growth and value creation in the market, and to use her external network and strategic thinking to closely connect to the innovation needs of the pharmaceutical industry. Amina is also an engaged thought leader and business advocate. She is an executive board member of the International Pharmaceutical Excipients Council (IPEC) in Europe, a lecturer at Zurich Federal Institute of Technology (ETH), and an active member of DuPont N&H Global Diversity & Inclusion Steering Committee since May 2018. Amina also engages in the community high schoolers on diversity & inclusion that is a key asset for a business growth and

Ann Gulau
International Flavors & Fragrances Inc., US

Ann Gulau is quality manager within the Pharma Solutions organization of the Nutrition & Biosciences division of DuPont. She has more than 20 years of experience in various quality assurance roles, supporting manufacture of drug substances and excipients. Ann is also chair of the Excipient Qualification committee of IPEC-Americas. Ann has a bachelor's degree in Materials Science and Engineering from the University of Florida in the United States.

Felix Hofmann
Evonik Operations GmbH | Nutrition & Care, Germany

Felix Hofmann is currently Director of Formulation & Application Services EMEA at Evonik Operatiions GmbH, Darmstadt, Germany.
From 2002 to 2005 he made an education as chemical laboratory technician at Röhm GmbH & Co.KG, Darmstadt, Germany including theory and practice in polymerization and application technology. In 2015 Felix completed his degree as a process engineer specialized in pharmaceutical technology at the university of applied science FH Bingen, Germany. The topic of his B.Sc. thesis was "Fluidized bed technology as an alternative to conventional spray drying technology for bioavailability enhancement of celecoxib by adsorption on solid carriers". Felix started his career in 2005 at the technical service laboratory for EUDRAGIT® polymers. From 2006 to 2008 worked as a Scientist and from 2008 to 2012 as a Senior Scientist looking after customer requests, customer projects and process troubleshooting during scale up and production of coated particles or tablets for northern Europe. From 2012 to 2015 he worked as a Principal Scientist with focus on complex customer projects including GMP and HPAPI requirements. From 2015 to 2017 he was responsible for evaluation, design and implementation of customer projects for pharmaceutical and nutraceutical oral dosage forms as Technical Project Coordinator. Until 2021 he worked as Manager Technical Sales with the responsibility of a holistic technical support for key and strategic accounts.

IPEC Europe Excipient Conference 2022

Speaker

Kelly-Kalliopi Vanderas
Hoffman La Roche, Switzerland

Kelly is a Postdoctoral scientist in Roche, Basel, in the formulationand process development department. Before joining Roche, Kellyheld a Teaching Fellow position at King's College London, UK, where she also didher graduate studies. She has been involved in several research projects focusedin studying drug solubility, drug-membrane interfacial interactions as well asdeveloping polymeric and liposomal formulations for inhaled and intravenousdelivery of anti infectives. Kelly is a registered Pharmacist in Greece, worked as aQC analyst in the Greek pharmaceutical company ELPEN before pursuing hergraduate studies. She has collaborated with the Science and Technology FacilitiesCouncil, UK, to conduct neutron scattering experiments, Public Health Englandfor performing microbiological assays and Novabiotics, Scotland, to perform formulation development of Novamycin from the company's antifungal peptideplatform.

Lotte Kok
Novo Nordisk, Denmark

Lotte Kok is quality assurance specialist in Novo Nordisk within thesourcing organisation supplying raw materials, APIs, excipients andprocess aids to Novo Nordisk sites worldwide. She has 30 years of experiencewithin the pharmaceutical industry and have a broad knowledge to many arease.g. research & development, manufacturing, regulatory affairs, pharmacovigilance, supplier management, quality control and quality assurance including theblood and tissue regulations. Lotte holds a bachelor's degree in biomedical science in biochemistry and a master of quality management (MPQM) from University of Southern Denmark.

Prof. Dr. Jean-Christophe Leroux
ETH Zürich, Switzerland

Jean-Christophe Leroux is a full professor of Drug Formulation and Delivery and head of the Institute of Pharmaceutical Sciences at the ETH Zurich, Switzerland. He has made important fundamental and applied contributions to the fields of biomaterials and drug delivery, and has been involved in the development of innovative bio-detoxification systems for the treatment of metabolite disorders. He is a fellow of the AAPS, EURASC and the CRS, and the co-founder of the start-up pharmaceutical companies Versantis AG and Inositec AG.

Prof. Dr. Karsten Mäder
Martin Luther University Halle-Wittenberg, Germany

Karsten Mäder is the head of Institute of Pharmacy at the Martin Luther University Halle-Wittenberg in Germany. He studied Pharmacy at the Humboldt-University in Berlin. After his Diploma and PhD he was a DAAD Postdoc scholar at the Dartmouth Medical School (NH, USA). He returned to the HU Berlin and completed with a DFG grant his Habilitation. After Postdoc positions ate the Philipps-University Marburg and the Free University Berlin he worked at Roche in Basle. Since 2003 he is Full Professor of Pharmaceutics at the Martin Luther University Halle-Wittenberg.
Main research areas include polymer-, lipid and phospholipid drug delivery systems (DDS), biodegradable parenteral controlled release dosage forms, noninvasive in vitro and in vivo characterization of DDS, and the enhancement of oral bioavailability. He published around 240 papers, several book chapters and patents. Karsten received several awards, including the Scheele-award of the German Pharmaceutical Society, the CRS - Capsugel award for innovative aspects in controlled drug release, the Young Investigator Award of the International EPR society, the "Pharma Technik"- award, and the APV Research Award for Outstanding Achievements in the Pharmaceutical Sciences.

Dr. Frank Milek, IPEC Europe Vice-Chair
Aug. Hedinger GmbH & Co. KG, 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 inpharmaceutical 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 working for more than 20 years inpharmaceutical 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 President of IPEC Federation, Chair IPEC Europe GDP Committee and vice-chair of the International Pharmaceutical Excipients Council Europe (IPEC Europe).

Tanja Natterer
Aug. Hedinger GmbH & Co. KG, Germany

Tanja Natterer studied pharmacy at the University of Tübingen and is a specialist pharmacist for pharmaceutical analysis.
She is working in the pharmaceutical quality control in the GMP Laboratory Hedinger, Stuttgart (Germany) since 2011. In her current function as head of quality control and Qualified Person acc. to §14 AMG she is responsible for multicompendial compliance testing of pharmaceutical excipients.

Professor, Ph.D. Jesper Østergaard
University of Copenhagen, Denmark

Jesper Østergaard is Professor of Pharmaceutical Physical Chemistry at University of Copenhagen. Main research interests include development of methods for physical-chemical characterization of drug substances and delivery systems, drug transport, dissolution and release. Focus is on the development of analytical methods for in vitro dissolution and release testing (including UV imaging), and on molecular interactions, sizing and stability assessment related to profiling of drug substances and delivery systems using capillary-based methods (FIDA, TDA and CE). Dr. Østergaard is a pharmacist (1999) and obtained his Ph.D. in pharmaceutics working on molecular interaction studies and prodrug design in Copenhagen in 2003. Subsequently, he became Assistant and Associate Professor (2003, 2006) and since 2019 Professor at Department of Pharmacy. He has published >140 scientific papers. Dr. Østergaard is the co-founder of two spin-outs from University of Copenhagen.

Catherine Sheehan, DRSc., MS., MS.
United States Pharmacopeia, US

Dr. Sheehan is currently the Senior Director of Growth Programs, Foods and Excipients under the Global Science and Standards Division at the United States Pharmacopeia (USP), Rockville, MD. In her current role, she is the Science co-lead for both the Excipients and Foods Program Units and is responsible for supporting USP's mission and priority initiatives for strengthening the global supply of quality medicines. Her responsibilities include developing a definitive source of quality standards and solutions throughout the pharmaceutical and foods lifecycle that include traditional standards, physical materials, and other tools. Her responsibilities also include partnering though USP's Stakeholder Engagement Model to improve awareness and advocating for adoption of new and up-to-date quality standards and related programs around the globe. Additionally, her role supports the Pharmacopeial Discussion Group (PDG) comprising the USP, European Pharmacopoeia and Japanese Pharmacopeia successfully harmonizing high priority excipient monographs and related excipient chapters undergoing harmonization as well as support of the USP Council of Experts, Excipient and Food Expert Committees. Dr. Sheehan is active in AAPS and RAPS. She holds a B.Sc. in Science from University College Cork, Ireland, an M.S. Regulatory Science degree and M.S. Molecular Biotechnology degree from The Johns Hopkins University and a doctoral in Regulatory Science, International Center For Regulatory Science, University of Southern California School of Pharmacy.

Dr. Mahmud Yunis, IPEC Europe Board Member
BIOGRUND, Germany

Dr. Mahmud Yunis has been working for 15 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.

Seminarregistration by fax +49 6131 97 69 69 or by e-mail apv@apv-mainz.de

Location

Scandic Frankfurt Museumsufer
Wilhelm-Leuschner-Straße 44
60329 Frankfurt am Main
Tel.:+49 69 9074 59 0
Fax: +49 69 907459 335

Date

Course no. 3255
from 27 September 2022 09:00 h
to 28 September 2022 16:30 h

Registration fee

Early Bird Fee *(until 30 June 2022)*
Industry 1490 EUR[1]
Authority/University 745 EUR[1]

Regular Fee *(from 01 July 2022)*
Industry 1590 EUR[1]
Authority/University 795 EUR[1]

([1]plus VAT)

Coffee breaks, lunch, dinner and electronic proceedings included.

Registration

APV-Headquarters
Kurfuerstenstraße 59
55118 Mainz/Germany
Phone: 0049 6131 97 69 0
Fax: 0049 6131 97 69 69
E-mail: apv@apv-mainz.de
Web: www.apv-mainz.de

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

Hotel reservation

Scandic Frankfurt Museumsufer
Wilhelm-Leuschner-Straße 44
60329 Frankfurt am Main
Tel.:+49 69 9074 59 0
Fax: +49 69 907459 335

We have blocked room allotments for ourparticipants in various hotels of differentcategories.
To book, please go to our homepage: https://www.apv-mainz.de/en/seminare/events/event/semi-

IPEC Europe Excipient Conference, 27-28 September 2022, Frankfurt am Main, Germany, Course no. 3255

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 APVI/IPEC uses my data for the purpose of processing the order and provides me with all relevant information.

☐ I also agree that APV/IPEC may contact me for the purpose of exchanging similar information by email or post.

Your data will not be shared with third parties. You have a right of withdrawal at any time without giving reasons.

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APV GmbH
Kurfürstenstraße 59
55118 Mainz/Germany
www.apv-mainz.de

Phone: 0049 6131 97 69 0
Fax: 0049 6131 97 69 69
E-mail: apv@apv-mainz.de

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Please select 2 of the following Workshops (please tick only 2)

☐ Data integrity – current experiences

☐ Internal analytical method harmonisation – an industry approach to safe testing resources

☐ Managing appropriate transport conditions for excipients – current situation and experiences

Your registration fee also includes the participation in the Welcome Reception on Monday, 26.09.2022 and the Social Event on the first conference day, 27.09.2022.
Please let us know if you wish to attent:

Welcome Reception (26.09.2022) ☐ Yes ☐ No

Social event (27.09.2022) ☐ Yes ☐ No