IPEC Europe Excipient Conference

2023

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

27 - 28 September 2023
Rotterdam • The Netherlands
Course no. 3272

incl. Workshops:

- Supplier Qualification – Challenges & Opportunities in each step of the process
- Nitrites everywhere – when do their levels matter, and what can be done to reduce/control a nitrosamine risk
- Stability testing of excipients - IPEC Stability Guide 2022

IPEC EUROPE 30 YRS APV

IPEC Europe Excipient Conference 2023

Dear Colleagues,

IPEC Europe and APV are delighted to invite you to our 11th annual conference on pharmaceutical excipients slated on 27-28 September 2023 in Rotterdam, The Netherlands.

The conference will be held on two days: from Wednesday (morning) until Thursday (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". We will open the conference with a presentation in IPEC Federation followed by a talk on Supply chain security and the related IPEC Federation position paper. The remaining of the presentations will cover current hot topics like recent FDA requirements for excipients supplier and the EMA Q&A on co-processed excipients.

The regulatory workshops aim to provide detailed practical information about current topics supporting industry to comply with regulatory requirements and other expectation. These "workshops" will be held two times in parallel to allow participants to attend two of the three sessions. These sessions will allow practical exercises and discussions related to the topics covered. Participants will have the opportunity to exchanges their personal experience with colleagues out of the same industrial and regula¬tory environment. The workshop topics will be on Supplier Qualification – Challenges & Opportunities in each step of the process, nitrites everywhere – when do their levels matter, and what can be done to reduce/control a nitrosamine risk and IPEC stability guide 2022.

Since excipients are key parts of the formulation of medicines, we will open the second day with a talk from USP on Novel Excipients followed by a presentation on "how will the FDA PRIME program support the development of new excipients". Afterwards we will take the opportunity to listen to a variety of subjects such as impacts of excipients on oral bioavailability, coated tablet performance, and the use of 3D printing for an efficient tablets production, an automated and DoE based development of oral solid dosage forms as well as the use of a complete line of excipients for hard-shell capsules.

We are looking forward to welcoming you in Rotterdam, The Netherlands.

Dr. Amina Faham
IPEC Europe Chair

Dr. Frank Milek
IPEC Europe Board Member

Dr. Mahmud Yunis
IPEC Europe Board Member

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IPEC Europe Excipient Conference 2023

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:

- Supplier Qualification – Challenges & Opportunities in each step of the process.
- What can be done to reduce/control a nitrosamine risk.
- IPEC stability guide 2022.

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

- Supply chain security and the related IPEC Federation position paper.
- FDA Warning Letter to an Excipient Company, need for higher Standards (Panel discussion).
- EMA Q&A on Co-processed Excipients.
- USP standards setting for excipients – present and future
- How will the FDA PRIME program support the development of new excipients?
- Investigation of the impact of coating imperfections on tablet performance.
- Use of 3d printing and excipients for the cheaper and faster production of tablets.
- Fully automated and DoE based development of oral solid dosage forms with the help of excipients.
- Dilu Cap: A Complete Line of Excipients for Hard-shell Capsules.

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.


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Programme Committee

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

Dr. Frank Milek
IPEC Europe Board Member
Aug. Hedinger GmbH & Co. KG, Germany

Dr. Mahmud Yunis
IPEC Europe Board Member
BIOGRUND, Germany

Programme

Tuesday, 26 September 2023 at 19:00 h

Participants and speakers are invited to join a welcome reception at the conference hotel.

Wednesday, 27 September 2023 08:30 - 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

IPEC federation position paper on supply chain security of pharmaceutical grade excipients

- Background information and history of fatal incidents caused by contaminated pharmaceutical products.
- World Health Organization (WHO) alarm and technical report on Good Trade and Distribution Practices for Pharmaceutical Starting Materials.
- Introduction to IPEC Federation Good Distribution Practices (GDP) Guide for Pharmaceutical Excipients and IPEC Federation GDP Audit Guide.
- Content of the updated 2023 IPEC Federation Position Paper on Supply Chain Security.

Rodrigo Arias, DFE Pharma, The Netherlands

Update Developments on Excipients at EDQM

- Update on European Pharmacopoeia activities on excipients
- Certification of suitability (CEP) and excipients
- CEP 2.0 implementation

Hilde Depraetere, EDQM, France

Coffee Break and Table Top Exhibition

Recent FDA feedback from FDA on their concerns about excipients

- The legal basis of FDA oversight of excipient manufacturing and supply

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Programme

- First ever Warning Letter to an excipient manufacturer
  - Was there anything new in these findings?
  - Impact for EXCiPACT and our plans to strengthen the Certification Scheme
  - What excipient manufacturers should do next?
- Benzene in drug products
- Ethylene and diethylene glycol adulteration of Propylene Glycol

Dr. Iain Moore, EXCiPACT, Belgium

Regulatory obstacles in the approval of medicines in Europe containing Co-processed excipients

- Co-processed excipients (CPE) are evaluated differently by European authorities compared to well-known excipients.
- Marketing Authorization Holders (MAHs) are required to provide more detailed information about CPEs than what is typically expected for well-known excipients.
- IPEC Europe is in contact with the European Medicines Agency (EMA) and the Quality Working Party (QWP) to establish common guidelines for the definition and requirements of CPEs in marketing authorizations for the European market.
- The current positions of the relevant authorities and IPEC Europe will be discussed.
- Guidance for submission of relevant information will be provided)

Darek Lewin, JRS Pharma GmbH & Co KG, Germany

Lunch Break and Table Top Exhibition

Workshops:

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

Workshop 1

Supplier Qualification – Challenges & Opportunities in each step of the process

- Step 1 - We decide - What are our criteria? Who are the potential suppliers?
- Step 2 - We consider - What are the requirements regulatory and otherwise?
- Step 3 - We identify - What is our process to qualify?
- Step 4 - We integrate - The new supplier in our business process.
- Step 5 - We monitor - The performance of the supplier & reassess the qualification status.

Sarbari Roy, Seagen, Switzerland

Workshop 2

Nitrites everywhere – when do their levels matter, and what can be done to reduce/control a nitrosamine risk

- Quick introduction to nitrosamines, and specific situations that are high risk for nitrosamine formation in the drug product.
- Control options that can be employed: excipients with low-level nitrites, higher local pH in the formulation, nitrite scavengers in the formulation.
- Overview on how are nitrites distributed across different type of excipients - introduction to the Lhasa database on nitrites
- Use of the IPEC questionnaire, what information a user (pharma company) expect a manufacturer to submit, what type of information can be shared

Leonardo Allain, Merck US, USA

Workshop 3

Stability testing of excipients - IPEC Stability Guide 2022

- The IPEC Federation Excipient Stability Guide For Pharmaceutical Excipients version 02 2022
- Stability Studies in Pharmaceutical Products and API's
- Examples of Stability testing programs for Excipients

Beverley A. Stout, GSK, UK

Philipp Hoch, Aug. Hedinger GmbH & Co. KG, Germany

Coffee Break and Table Top Exhibition

Repetition of Workshops:

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

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.

Thursday, 28 September 2023 **09:00 - 16:30 h**

USP standards setting for excipients – present and future

- USP's strategy for novel excipients
- Excipient monograph updates related to the recent publication of the 2023 FDA guidance on testing for DEG and EG in high-risk excipients
- USP's update on nitrites in high risk Excipients

Dr. Catherine Sheehan, USP, US

How FDA's PRIME program will support future Novel Excipient Development – Requests for Additional Flexibility by Industry

- A brief history of how the PRIME program was developed from IPEC-Americas and IQ Consortium proposals
- Description of the initial Pilot Phase of the program, pilot candidates and current status of the program

- Expected uses of the PRIME program, once finalized and it's potential impact on innovation in drug and novel excipient development
- The need to globalize and harmonize this type of approach to novel excipients to maximize benefits
- New efforts from IPEC-Americas and the IQ Consortium for further flexibility related to the development and use of Co-processed Excipients

Dave Schoneker, IPEC America, US

cGMP natural and synthetic phospholipids for complex drug delivery systems and vaccines

- Introduction to Phospholipids
- Role of Phospholipids in:
  - Vaccines
  - Pulmonary Applications
  - Depot Injectable Formulations

Peter van Hoogevest, Lipoid, Germany

Coffee Break and Table Top Exhibition

Investigation of the impact of coating imperfections on tablet performance

- Film Coating in Drug Delivery
- Impact of coating imperfections on tablet performance
- Troubleshooting to resolve coating imperfections.

Elise Vaes, Janssen Pharmaceuticals, Belgium

Lunch Break and Table Top Exhibition

Future trends in drug product development - Additive manufacturing of oral dosage forms

- 3D printing technologies and their applications:
  - Personalized versus industrial settings
  - Opportunities and challenges of pharmaceutical 3D printing
- How to evolve 3D printing technology? - Interdisciplinary collaboration is key for success

Nadine Gottschalk, Merck, Germany

Fully automated and DoE based testing of excipients and development of oral solid dosage forms

- Quality-by-design
- DoE
- Automated development and testing
- Tablet compression and capsule filling

Thomas Brinz, Syntegon, Germany

Coffee Break and Table Top Exhibition

Improving excipient formulations for compounding pharmacies with DiluCapTM, a line of ready-to-use excipients for hard-shell capsules

- Particularities of the pharmaceutical compounding sector
- The need of grouping drugs according to the Biopharmaceutical Classification System
- Developed algorithm to assist in decisions
- Stability and performance studiess

Hudson Polonini, Fagron, The Netherlands

Closing remarks

Table Top Exhibition

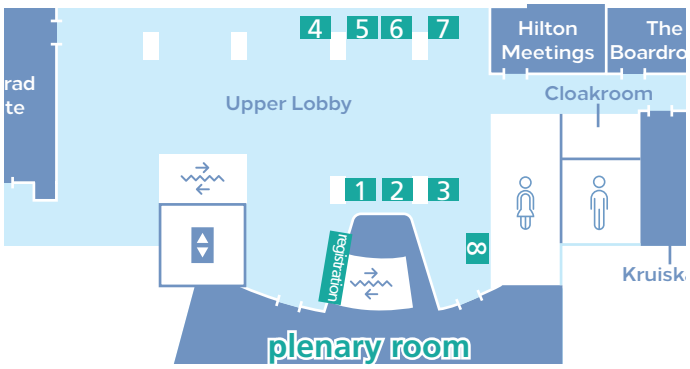
As well as in the last years, we are offering you the opportunity to present your company, products and services to a truly focused target market. Here you can reach everyone dealing with excipients without wastage.

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



Exhibitors:

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Sponsors:

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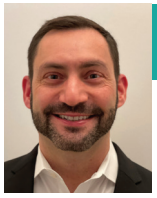
Speaker

Rodrigo Arias Dias
DFE Pharma, Germany

Technical Sales Manager Direct Business EMEA Rodrigo Arias holds a degree on industrial and process engineering, a master's in international business and diplomas on pharmaceutical production processes, high speed tableting, and international logistics. He worked at Novartis manufacturing site in the engineering projects and maintenance department. At DFE Pharma, since 2010, he has had several responsibilities in Latin America and EMEA regions, always with focus on tech support and quality-based sales. He has joined key tasks such as QbD training for global distribution network and business development for 3D printing and Dry Powder Inhalation. Since 2020 a permanent member of the GDP committee at IPEC Europe.



Leonardo Allain,
Merck US (MSD), US

Leo Allain, Ph.D., is a Distinguished Scientist with MSD, and has over 20 years of experience in pharmaceutical development, where he has led CMC teams responsible for several product approvals in multiple countries. He has authored guidances on the development of sterile products, ophthalmic and topical creams, photostability, nitrosamine formation in solids, and has expertise in the development of chemically unstable APIs in lyophilized products, injectables, and amorphous dosage forms. Leo is the author of over 45 publications and patents, and a guest lecturer for the USP, Sindusfarma, ANVISA and AAPS on pharmaceutical impurities, degradation mechanisms, photodegradation, including mutagenicity and nitrosamine assessment and derisking strategies. He is a member of the IQ working group on nitrosamines and the Lhasa Industry consortium on nitrite in excipients.

Thomas Brinz
Syntegon, Germany

Dr. Thomas Brinz received his doctorate in 1993 from the University of Ulm on liquid crystalline polymers, where he subsequently also worked as a post-doc. 1995-2003 he was employed in the Corporate Research department of Robert Bosch GmbH for the development of new functional material. 2003-2016 he founded the Bosch Lab Systems division Systems for automation solutions in formulation development (High-Throughput Formulation Systems). Since 2009 he has been responsible for the Engineering Pharma Service department (first at Bosch Packaging Technology and now at Syntegon Technology) and the OSD Customer Center.

Hilde Depraetere
EDQM, France

Dr Hilde Depraetere, PhD in Biochemistry from the University of Leuven, Belgium, has more than 20 years' experience in regulatory affairs in Industry and non-for profit organisations. Her main field of expertise is CMC and inspection related. In 2021 she joined the EDQM Certification of Substance department as Head of Scientific Support and Inspection.

Amina Faham, IPEC Europe Board Chair
International Flavors & Fragrances Inc., CH

Amina is a highly effective and passionate senior leader with several years of experience in leadership, generating business growth thru building highly performing technical teams, technology expertise and creating value for customers utilizing business acumen. Amina is a Biochemist with a Ph.D. degree in Pharmaceutical Sciences from school of Pharmacy, University de la Mediterranean France. She has over 15 years of Healthcare industry experience and have worked for several pharmaceutical and excipients companies. Amina offers an array of skills in customer-centric thinking, people leadership, strengthening and evolving competitive business landscape and driving and implementing strategic innovation Amina started as R&D leader at Ethypharm Canada, where she was responsible for developing new technologies in modified release oral solid dosage forms (OSDF). She then joined Pfizer Pharmaceutical Canada as global head of prescription drugs R&D group. Since joining Pharma Solutions at DOW Switzerland in 2011, Amina has held roles of increasing responsibility starting as pharma application development leader for EMEA, applying her deep technical expertise into business results by supporting products and customers. She then moved into leadership roles within R&D and commercial organizations. Through the DuPont and IFF mergers, Amina played an integral role in building a strong market-face scientific team from all heritage businesses to ensure business continuity and talent retention. She now leads the global research & development for Pharma Solutions and her main responsibilities are to build, develop and lead high performing global technical team for high impact on business growth and value creation in the market, use her deep technical expertise, external network and strategic thinking to closely connect to the innovation needs of the healthcare industry, and ensures that R&D and commercial strategies are aligned. For several years, Amina has been an engaged thought leader and business advocate in the market. She is the chair of the board of the International Pharmaceutical Excipients Council in Europe and a lecturer at Zurich Federal Institute of Technology (ETH). She also engages in the community high schoolers on diversity & inclusion that is a key asset for a business growth. Amina and her family have lived in multiple countries and continents, experienced different cultures, languages, foods and has made priceless discoveries and memories.

Nadine Gottschalk
Merck, Germany

Nadine Gottschalk studied pharmacy at the Johannes Gutenberg University in Mainz, Germany, and joined the department "Pharmaceutical Technologies" at Merck Healthcare in 2019 to pursue a PhD on the topic 3D printing of poorly soluble drug substances. She gathered expertise in extrusion- and powder-based 3D printing techniques as well as in the field of amorphous solid dispersions. Since 2022, she works as a principal scientist at Merck Life Science. As part of the solid formulation R&D team within Process and Formulation Materials she is focusing on product development for solubility enhancement and advanced manufacturing technologies.

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Speaker

Philipp G. Hoch
Aug. Hedinger GmbH & Co. KG, Germany

Dr. Philipp G. Hoch started his carrer in 2016 at Hedinger as a QA/QC-Manager. Thereafter, he broadened his knowledge at LTS in Andernach, Germany, where he worked as a QA-Manager in the field of Micro Array Patches and at Rentschler Biopharma SE in Laupheim, Germany, where he established a quality control laboratory for mRNA based COVID-vaccines and took the lead of the quality control laboratory for bioanalytical methods. During this time he contributed the one of the first publications on CQAs of mRNA based drugs which was published in July 2023. In September 2023 he rejoined Hedinger in the area of QA and regulatory compliance.

Darek Lewin
JRS Pharma GmbH & Co KG , Germany

Darek Lewin graduated in „Technology of Renewable Raw Materials“ from the University of Applied Sciences Hannover in 2001. In 2003, he joined JRS in Rosenberg, Germany, as a Project Manager for „Microencapsulation of Probiotic Bacteria.“ Over the years, Darek has held several key positions within the organization. From 2004 to 2006, he served as the manager for food and feed safety, and later as the head of corporate quality at JRS Pharma. Since 2007, he has been leading the quality department for the entire JRS Group, with more than 40 production sites across Europe, the USA, India, China, and Mexico. The JRS Group provides solutions for various applications and chemical processes for almost every field of daily life with their fiber products. JRS Pharma, as a member of the JRS Group, is a leading manufacturer of excipients, offering comprehensive solutions to the global health science industry. In addition to the wide range of excipients, JRS Pharma provides technical and regulatory support to address the needs and formulation challenges of their customers. JRS is an active member of IPEC. Within IPEC Europe, Darek contributes to the Co-Processed Excipients Task Force and the QRA-Committee.

Frank Milek, IPEC Europe Board Member
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 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 working for more than 20 years in pharmaceutical excipient industries, especially in the field of supply chain, distribution and manufacture. Frank is anexpert 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 chair of the IPEC Europe GDP Committee and board member of the International Pharmaceutical Excipients Council Europe (IPEC Europe).

Iain Moore
EXCiPACT, Belgium

Dr Iain Moore graduated with a Ph.D. in Chemistry from the University of Bristol and is the Global Head of Quality Assurance a Croda International, a supplier of many types of high purity excipients, APIs and vaccine adjuvants. He has held a range of QA roles in Croda for over 25 years, including implementing ISO and GMP standards across the group, including hosting regulatory inspections to API GMP standards. He has contributed to the publication of both European and US National Standards, and the development of the EFfCI GMP Guide for Cosmetic Ingredients. He is the current chair of the EFFCI GMP Committee which oversees the associated certification scheme for cosmetic ingredients. He has been an active participant of IPEC Europe for nearly 20 years, contributing to the development and revision of numerous guides including the famous IPEC-PQG GMP Guide for Pharmaceutical Excipients 2006, but more recently, the PDA-IPEC Technical Technical Report 54.6, Formalised Risk assessment for excipients, 2019, the IPEC Federation GMP Certification Scheme and Certification Qualification Guide 2020, the IPEC Federation Excipient Information Package, Part IV: Sustainability Overview, 2023, and the IPEC Federation Questionnaire for Excipient Nitrosamines Risk Evaluation, 2023. He was instrumental in the team that took the IPEC-PQG GMP Guide 2006 and converted it to the EXCiPACT Certification Scheme for Pharmaceutical Excipients. He has served as President for two terms and is currently an expert advisor to the EXCiPACT association.

Hudson Poloni
Fagron, The Netherlands

Hudson Polonini (MSc, PhD) is a pharmacist with 13 years of experience in the compounding market. He has been working with quality control, quality assurance, and developing innovative personalized pharmaceuticals and cosmetics. Currently, he works as Global R&D Manager at Fagron Global Services Center. He has published more than 90 scientific articles in peer-reviewed journals, as well as 6 books for the health sciences. His areas of expertise related to formulation development are topicals and transdermals, oral solid and liquid pharmaceuticals, innovative dosage forms, drug delivery, in vitro and in vivo testing.

Sarbari Roy
Seagen, Switzerland

Sarbari Roy is the Head of External Quality in Seagen. Her group manages all external interactions for Seagen. Scope of this group includes managing suppliers and vendors in addition to CMOs and CTOs. She has over 30 years of industrial experience within Pharmaceutical and Biotech industries. In her carrier she managed multiple Sterile and Biotech manufacturing sites as Head of QA in multiple countries in Europe. She also headed Audit function both in divisional level (Suppliers & CMOs & CTOs) and corporate level (Internal manufacturing sites, PAI readiness) and herself is a certified auditor. She was recognized by the Swedish Regulatory Agency (MPA) as a Qualified Person in accordance with EU regulations and Deputy Responsible Person in Switzerland by Swiss Medics. She is a passionate advocate of continuous improvement of business processes and led/project managed multiple cross functional CI and IT system implementation projects. Since 1996 she is a member of senior leadership teams in multiple companies and recognized as a strong leader in her field.

IPEC Europe Excipient Conference 2023

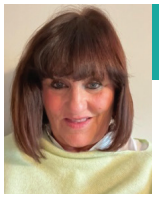
Speaker

David R. Schoneker, IPEC America
Black Diamond Regulatory Consulting, LLC, US

David R. Schoneker is currently the President/Owner of Black Diamond Regulatory Consulting, LLC, a consulting firm specializing in providing regulatory and quality consulting for the pharmaceutical, dietary supplement, food and related industries. The firm provides expert advice for difficult problems and training on excipient and food additive regulatory, quality and supply chain concerns. With over 45 years of experience working in these areas, Dave has developed strong networks with trade associations, regulatory agencies and pharmacopeias around the world. He is also an Adjunct Professor at Temple University's School of Pharmacy in their RA/QA Master's Program teaching courses in Global Excipient Regulations and the Regulation of Dietary Supplements. Prior to August 2019, David R. Schoneker was the Global Regulatory Director – Strategic Relationships at Colorcon, Inc. His responsibilities included global coordination of Colorcon's worldwide regulatory activities. He was at Colorcon from 1977 until 2019. Mr. Schoneker was the Chairman of IPEC-Americas during the period 2007-2009 and is currently a member of the Executive Committee, the Chair of the QbD/Composition Committee and is actively involved with the development of Regulatory, Safety, GMP and Supplier Qualification related guidelines to improve Excipient Quality and Safety.

Catherine Sheehan
United States Pharmacopeia (USP), 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 responsible for both Excipients and Foods supporting USP's mission and priority initiatives for strengthening the global supply of quality medicines and foods. Her responsibilities include developing a definitive source of quality USP-NF and FCC standards and solutions throughout the pharmaceutical and food lifecycles that include traditional standards, physical materials, and other tools and solutions. Her responsibilities also include partnering through USP's Stakeholder Engagement Model to improve awareness in 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, Japanese Pharmacopeia, and the India Pharmacopoeia pilot 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, a 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, from University of Southern California School of Pharmacy.



Beverley A. Stout
GSK, UK

Bev Stout is a Global Supplier Quality Manager at GSK based in the North East of England managing a number of key excipient suppliers used in various dose forms including inhaled, oral solid dose, topical and Biopharm products. She has worked at GSK for 37 years in Microbiology, Validation and Supplier Quality. She has a BSc Honours Degree in Biotechnology with Management from Thames Valley University and a Higher National Certificate in Biomedical Science specialising in Medical Microbiology. Bev has represented GSK on the IPEC Europe Quality & Regulatory Affairs Committee since 2010 and has contributed to a number of new and revised IPEC guides including the revised IPEC PQG GMP guide issued in 2022 as well as number of EXCiPACT standard revisions (2017 GMP/GDP revision and PAMS guide 2023) She is also a member of the IPEC Europe Annual Event Committee.

Elise Vaes
Janssen Pharmaceuticals, Belgium

Elise Vaes is a scientist with over 7 years of experience in the oral solid development at Janssen R&D. In this role, she is responsible for end-to-end drug product formulation and process development and serves as a subject matter expert in formula and process development for film coating, ensuring Best Product and Process at Launch. Elise has a master's degree in Drug Development, and an advanced master's degree in Industrial Pharmacy from KU Leuven University in Belgium.

Peter van Hoogevest
PHARMANOVATION and Lipoid, Germany

Peter van Hoogevest, is a pharmacist by training (Utrecht University in The Netherlands), who got his PhD degree in biochemistry 1984 at the Utrecht University in The Netherlands. In 1994 he received the degree of Privatdozent (adjunct professor) in pharmacy at the University of Basel, Switzerland. His industrial career started at the Biovet Group of the Animal Health Division of Ciba-Geigy Ltd. (Basel) in 1984. Shortly thereafter he obtained a position at the Novel Dosage Form Department of Pharmaceutical Development of the Pharmaceuticals Division of Ciba-Geigy Ltd. After having several positions at this department at Ciba Ltd. and Novartis Ltd. he founded in 1998 together with colleagues of the Pharmaceutical Development Department and reputed industrial managers and scientists the company ADD Advanced Drug Delivery Technologies (Muttenz, CH) and became CEO of this company and was member of the Board of Directors. In 2000 he joined Phares Drug Delivery AG (Muttenz, CH), a company specialized in the delivery of poorly water soluble drug substances, as Managing Director and COO and member of the Board of Directors. From 2012 till 2021 he was Managing Director of the Phospholipid Research Center, Heidelberg and Head of the Scientific Department (including the Development Department) of Lipoid GmbH, Ludwigshafen am Rhein, Germany). He runs from 2021 on his own consulting business PHARMANOVATION, based in Rheinfelden (Baden) , Germany. His drug delivery expertise, especially in the (phospho)lipid research and development area, is underscored by 79 scientific publications, including 8 book chapters, 33 symposium posters, co-promotion of 48 PhD Theses, 13 patents and 45 patent applications.

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.

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

MAKING SCIENCE WORK

Location

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The Netherlands
Tel: +31 (0)10 710 8011
mail events.rotterdam@hilton.com

Date

Course no.: 3272
from 27 September 2023 09:00 h
to 28 September 2023 16:30 h

Registration fee

Early Bird Fee *(until 30 June 2023)*
Industry 1590 EUR[1]
Authority/University 795 EUR[1]

Regular Fee *(from 01 July 2023)*
Industry 1690 EUR[1]
Authority/University 845 EUR[1]

([1]plus VAT)

Coffee breaks, lunch, dinner and electronic proceedings included.

Registration

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E-mail: apv@apv-mainz.de
Web: www.apv-mainz.de

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

Hotel reservation

Hilton Rotterdam
Weena 10
3012 CM Rotterdam
The Netherlands
Tel: +31 (0)10 710 8011
mail events.rotterdam@hilton.com

We kindly ask you to book your hotel yourself.
We have blocked a limited contingent on the special rate of 199,00 € incl. breakfast. Reservation via link (click here). Special rates available until 15 August 2023.

IPEC Europe Excipient Conference 2023 , 27 - 28 September 2023, Rotterdam, The Netherlands, Course no. 3272

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

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

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

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

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

Declaration of consent in respect of data protection

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

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All other information can be found in our privacy policy (www.apv-mainz.de/en/imprint/data-protection-statement/) , (www.ipec-europe.org/privacy.html).

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☐ Supplier qualification – Challenges & Opportunities in ...

☐ Nitrites everywhere – when do their levels matter, and what ...

☐ Stability testing of excipients - IPEC Stability Guide 2022

Your registration fee also includes the participation in the Welcome Reception on Tuesday, 26.09.2023 and the Social Event on the first conference day, 27.09.2023.

Please let us know if you wish to attent:

Welcome Reception (26.09.2023)		Social Event (27.09.2023)	
☐ Yes	☐ No	☐ Yes	☐ No