IPEC Europe Excipient Conference

2024

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

24 - 25 September 2024
Vienna • Austria
Course no. 3292

incl. Workshops:

- New IPEC Federation GDP Guideline
- Change Control Guideline
- How to provide Regulatory Information for Excipients: from both sides - from the user's perspective and from the manufacturer's perspective

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IPEC Europe Excipient Conference 2024

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Dear Colleagues,

IPEC Europe and APV are delighted to invite you to our 12th annual conference on pharmaceutical excipients slated on 24-25 September 2024 in Vienna, Austria.

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". We will open the conference with a presentation on IPEC Federation, followed by a talk on Pharmacopeia matters from EDQM. The remaining of the presentations will cover current critical topics like excipients quality, composition & impurities, excipient taxonomy for the 21st century, and an approach to computerized system validation.

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, 1- New IPEC federation GDP Guideline, 2- Change control guidelines, and 3- How to provide regulatory information for excipients.

Since excipients are key parts of the formulation of medicines, we will open the second day with a presentation on data integrity. Afterwards, we will take the opportunity to listen to a variety of subjects such as excipients selection for soft capsules product development, and innovative approach for taste masking to enhance patient compliance. This year, we will have a stronger focus on biologics with three (3) topics: digitalization of biologics manufacturing process, stabilizer for Biopharmaceuticals, and new approaches for drug delivery utilising extracellular vesicles.

We are looking forward to welcoming you in Vienna, Austria.

Dr. Amina Faham
IPEC Europe Chair

Dr. Frank Milek
IPEC Europe Board Member

Dr. Mahmud Yunis
IPEC Europe Board Member

IPEC Europe Excipient Conference 2024

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:

- New IPEC Federation GDP Guideline
- Change Control Guideline
- How to provide Regulatory Information for Excipients: from both sides - from the user's perspective and from the manufacturer's perspective

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

- EDQM update on pharmacopeial matters.
- Excipients: USP focus and update on quality, composition, and impurities.
- Excipient taxonomy for the 21st century.
- An approach to computerized system validation.
- Excipient selection in soft capsule product development.
- Enhancing patient compliance: Innovative approaches of taste masking.
- Digitalization for manufacturing process development of biologics drug product (fill & finish).
- Stable stabilizer for biopharmaceuticals.
- Exogenous loading of extracellular vesicles.

Target group

This conference is aimed at professionals working in the following areas:

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

The seminar is also aimed at employees 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

Monday, 23 September 2024 at 19:00 h

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

Tuesday, 24 September 2024 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

EDQM update on pharmacopeial matters

- What's new at EDQM?
- New development on excipients in the Ph. Eur.
- DEG/EG adulteration - status update on Ph. Eur. actions
- Progress of the CEP for excipients

Anne Garnier, EDQM, France

Excipients: USP Focus and Update on Quality, Composition and Impurities

- Introduction to USP and USP-NF
- USP Excipient Standards and Solutions
- DEG/EG Contamination: Updates
- Nitrites in Excipients: Perspective of USP

Christian Zeine, USP, Switzerland

Coffee Break and Table Top Exhibition

Excipient Taxonomy for the 21st Century: A grand challenge for the pharmaceutical sciences community

- Patients, regulators, payers, and consumer advocates are becoming increasingly focused on the non-active materials used in human drug products

IPEC Europe Excipient Conference 2024

Programme

- The current approach to describing and specifying these materials is outdated and inadequate for the needs of the 21st century
- The excipient user and supplier community urgently needs to develop a comprehensive excipient taxonomy approach to support the development of today's highly complex drug delivery systems
- This presentation will highlight the costs and benefits for formulators, excipient suppliers, regulators, and patients of such an enhanced system of excipient taxonomy

Bruno C. Hancock, Aleurites LLC, USA

An Approach to Computerized System Validation

- What can a structured approach to CSV look like?
- What requirements arise from it for the organization?
- What are the key challenges and success factors?

Susanna Ralev, BASF, Germany

Lunch Break and Table Top Exhibition

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

Workshop 1

New IPEC Federation 2024 GDP Guideline

- Background and history of fatal incidents caused by contaminated pharmaceutical products
- Introduction to the new 2024 IPEC Federation Good Distribution Practices (GDP) Guide for Pharmaceutical Excipients
- Awareness on GDP's by the pharmaceutical industry and all other players involved in the pharmaceutical supply chain
- Enforcement, Adherence, and Compliance to GDP's and GMP's

Rodrigo Arias, DFE Pharma, The Netherlands
Allan Whiston, QA Resolutions, UK

Workshop 2

Change Control Guideline

- Analyze perspectives of manufacturers and users in pharmaceutical change control.
- Focus on regulatory requirements and their mutual impacts.
- Aim to deepen understanding and recognize limitations of manufacturer and user.
- Use practical examples to apply and compare guidelines in groups.
- Enable participants to interpret guidelines and understand requirements.

Darek Lewin, JRS Pharma GmbH & Co KG , Germany
Lotfi Bouchekioua, Merck & Cie KmG, Switzerland

Workshop 3

How to provide Regulatory Information for Excipients: from both sides - from the user's perspective and from the manufacturer's perspective

Beverley A. Stout, GSK, UK and
Amiee Allen, Colorcon, UK

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 trough the Schönbrunn Castle Parc with networking dinner at the traditional Brendauer Schlossbräu. Come and meet colleagues and specialists in the field of excipients around the world in an enjoyable and relaxed atmosphere.

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Wednesday, 25 September 2024 09:00 - 16:30 h

Data integrity for pharmaceutical excipients, what is important

- Regulatory requirements and recommendations
- Basics for compliance with data quality and data integrity
- Warning letters and their consequences and examples of findings

Eberhard Kwiatkowski, Pharmadvantage, Germany

Nanomaterials: Current Regulatory Position and Public Opinion

- What is the regulatory position of nanomaterials in Europe?
- Why are nanomaterials seen as a hazard by some agencies?
- What is an "engineered nanomaterial" v a long established excipient that has always contained incidental nanoparticles?
- How will the concern on nanoparticles in foods impact pharmaceuticals?

Kevin Hughes, Colorcon, UK

Excipient selection in soft capsule product development

- Fill formulation concepts
- Understanding shell/fill interactions
- Shell formulation strategies
- How to address bioavailability and stability issues
- Regulatory aspects and market needs

Gabriele Reich, University of Heidelberg, Germany

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Coffee Break and Table Top Exhibition

Enhancing patient compliance: Innovative approaches of taste masking

- Introduction to taste masking technologies to enable a patient centric approach for new developments
- The role of excipients to modify the physical properties of drug products to prevent the direct contact with taste receptors by coating or encapsulating with a barrier membrane: Case studies with ethyl cellulose
- Use of flavors for changing the organoleptic properties to improve perception of taste

Carsten Huettermann, International Flavors & Fragrances (IFF), Germany

Lunch Break and Table Top Exhibition

The Role of Excipients in Tabletting

- reasons for using functional excipients, API-driven challenges
- Importance of excipient type
- Functionality Related Characteristics (FRCs) of Excipients

Marek Lachmann, Biogrund, Germany

Stable Stabilizer for Biopharmaceuticals – The Quest for Polysorbate Alternatives

- development and characterization of novel alternative surfactants for biopharmaceuticals

Leonie Schneider, Novartis, Switzerland

Coffee Break and Table Top Exhibition

Exogenous loading of extracellular vesicles

- Extracellular vesicles (EVs) are natural nanostructures that carry a variety of molecules like proteins and nucleic acids (NAs).
- They play a key role in cell-to-cell communication, making them interesting systems for treating various diseases.
- However, the process of loading EVs with hydrophilic compounds (such as NAs) without compromising their structure and functionality remains challenging.
- In this work, two approaches for loading EVs with drugs will be presented, namely the osmotic shock and hybridization with non-lamellar lyotropic liquid crystal nanoparticles

Jean-Christophe Leroux, ETH Zürich, Switzerland

Closing remarks

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Table Top Exhibition

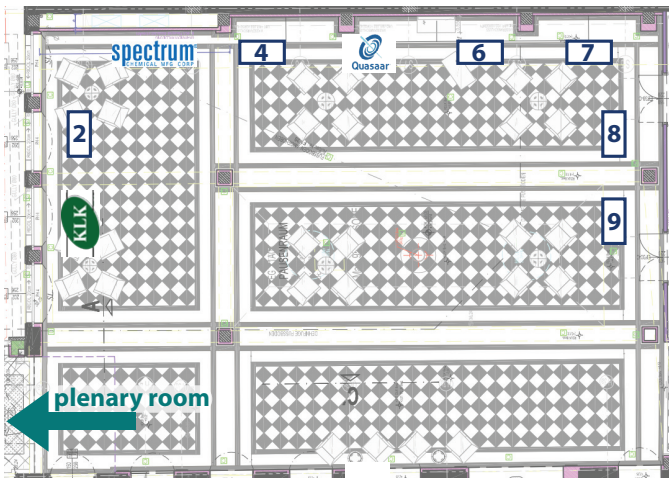
As in previous years, we offer you the opportunity to present your company, products and services to a truly focused target market. Here you can reach everyone dealing with excipients without wastage.

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



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Many thanks to our sponsors:

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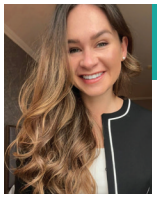
IPEC Europe Excipient Conference 2024

Speaker

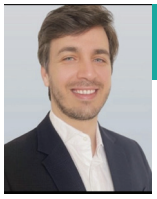
Rodrigo Arias
DFE Pharma, Germany

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.



Amiee Allen,
Colorcon, UK

Amiee works as the Regulatory Affairs Manager (EMEA) at Colorcon. Prior to this position, she was involved in Global Regulatory Affairs at Pfizer UK, managing UK/IE eCTD and non-eCTD dossier submission and oversight of two GB Covid-19 products. Amiee has previously worked in a Quality Assurance pharmaceutical position and is a Registered Biomedical Scientist (with extensive experience in both clinical practice and laboratory medicine). Amiee holds an MSc in Healthcare Management from the University of Greenwich and has earned postgraduate certifications in Critical Care Science and Quality Management Systems.



Lotfi Bouchekioua,
Merck & Cie KmG, Switzerland

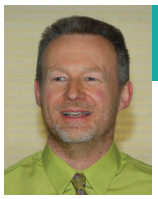
Lotfi Bouchekioua is an experienced Regulatory Affairs professional with a strong background in regulatory compliance, particularly in the pharmaceutical and medical device industries. He holds a Master's degree in French Health Law from Toulouse (2018-2019) and completed his pharmacy studies at the University of Pharmacy in Tours (2009-2015). Lotfi has held various roles, including Regulatory Affairs CMC Manager at Merck in both Ireland (2020-2022) and Switzerland (2023-present), and Regulatory and Quality Compliance Manager at Takeda in Switzerland (2022-2023). His expertise includes overseeing regulatory submissions, lifecycle management, and ensuring compliance with global health authority requirements. Additionally, he has experience with technical file preparation for CE marking and 510k submissions.

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.

Anne Garnier-Poidevin
EDQM, France

Mrs Anne Garnier-Poidevin is scientific program manager in the European Phamacopoeia department of the European Directorate for the Quality of Medicines & HealthCare (EDQM). She is pharmacist with a Master's degree in European Community Law and Pharmaceutical Regulation. Since 2005, she worked with responsibilities for a number of Expert Groups in the field of chemical substances and excipients. She further coordinates the pharmacopoeial harmonisation (e.g. Pharmacopeial Discussion Group (PDG)) activities within the EDQM..



Bruno C. Hancock,
Aleurites LLC, USA

Bruno C. Hancock is recently retired from a successful 25-year career at Pfizer Inc. and he is now working as an author, editor, teacher, and independent consultant to the pharmaceutical industry. Bruno most recently led the global materials science group within Pfizer's R&D division. This group was responsible for identifying the preferred solid and particulate forms of Pfizer's active pharmaceutical ingredients (APIs), and for enabling their rapid commercial development. Bruno holds a bachelor's degree in Pharmacy from the University of Bath, UK and a Ph.D. in Pharmaceutical Technology from the University of Bradford, UK. Dr. Hancock has worked in the areas of formulation development, spray dried dispersions, powder technology, pharmaceutical materials science, drug product process development, technology transfer, regulatory strategy, technical due-diligence, and computational drug product design. He has contributed to the commercialization of multiple human medicines, including Vioxx™, Xeljanz™, Cibinqo™, Paxlovid™, Daurismo™, Ibrance™, Litfulo™ and Xalkori™. Dr. Hancock has published over 140 full research papers and has contributed to more than 14 published patents. His papers have received over 20,000 citations and he has four publications that have each been cited more than 1000 times. Dr. Hancock has mentored

Speaker

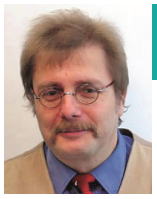
over fifty undergraduates (coop-students & interns), graduate students, post-docs and supervisees. He has acted as an expert advisor to the United State Pharmacopeia (USP) on the properties of pharmaceutical excipients since 1995 and he is a Fellow of the American Association of Pharmaceutical Scientists (AAPS). He currently serves as an Editor for the Journal of Pharmaceutical Sciences and the Handbook of Pharmaceutical Excipients.

Carsten Hüttermann
International Flavors & Fragrances (IFF), Germany

Carsten Huettermann studied Chemistry and gained his PhD in Macromolecular Chemistry from the University of Braunschweig, Germany. He started his career in 2002 at Wolff Walsrode AG, Bayer, as project leader with a focus on synthesis of new cellulose derivatives. Since 2006 he was head of the laboratory for regulated applications (Food, Pharma). In 2007 Wolff Walsrode AG evolved to Dow Wolff Cellulosics and later to DuPont and IFF. At this time Carsten was head of Research and Development (R&D) for food additives first in Europe and from 2010 on with a global responsibility. In May 2015 he changed to the pharma excipients group of Dow (now IFF) and is working since then as scientist for pharma applications responsible for technical support and key customer projects in Europe. Since 2018 he is also leading the Pharma Application Development & Innovation team of IFF Pharma Solutions in Europe. His fields of expertise are polymer science and on oral solid dosage forms with a focus on excipients and controlled release applications and capsules. He is author and co-author of several patents and scientific publications and presentations.

Kevin Hughes, IPEC Europe President
Colorcon, UK

Kevin Hughes, BSc (Hons), Regional Regulatory Director - EMEA. Kevin has been with Colorcon for over 20 years where he has been the Technical Expert in film coating, immediate release and extended release excipients. Kevin is now Regional Regulatory Director for Colorcon and is responsible for the EMEA region, providing regulatory support to customers in both the pharmaceutical and food industries, monitoring regulatory changes and industry initiatives setting regional regulatory strategy.. Kevin is President of IPEC Federation and on the board of IPEC Europe, actively participates in the IPEC Quality and Regulatory Affairs Committee as chair of the Titanium Dioxide, Nanomaterials and Microplastics task forces, he also represents IPEC on the board of EUPFI (European Pediatrics Formulation Initiative). Prior to joining Colorcon Kevin spent 5 years at Boots Healthcare Development, where he was Team Leader developing solid oral dosage forms for Boots Pharmacies. Kevin graduated with a BSc (Hons) degree in Food Science from Nottingham University in 1994. He has been involved in the pharmaceutical industry for 25years. Over this time he has built up a strong level of expertise in the development and manufacture of solid oral dosage forms.



Eberhard Kwiatkowski
Pharmadvantage, Germany

Eberhard Kwiatkowski has been involved in the validation of computer-based systems since 1995. After various positions at Bayer AG, including QA IT manager at the Elberfeld site, he has been working as a consultant for IT issues in the pharmaceutical industry since 2012. Mr Kwiatkowski is head of the SIG „Raw Data Definition“ and „Audit Trail Review“, co-author of the ISPE Good Practice Guide for auditing external suppliers and member of the GAMP®DACH Forum

Marek Lachmann
Biogrund, Germany

Marek is a pharmaceutical scientist and engineer. He held several positions as a Senior Reseacher, Innovation and Application Development Manager and Technical Manager in international pharmaceutical companies. The passionate researcher works at BIOGRUND GmbH as Head of Research where he is responsible for the development and optimisation of modern ready-to-use tableting and film coating premixes.

Jean-Christophe Leroux
ETH Zürich, Switzerland

Jean-Christophe Leroux is a full professor of Drug Formulation and Delivery at 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, French Academy of Pharmacy, and the CRS, and was the co-founder of the start-up pharmaceutical companies Versantis AG, Inositec AG and Obaris AG.

Darek Lewin
JRS Pharma GmbH & Co KG , Germany

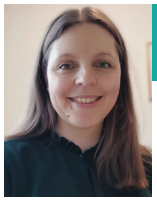
Darek Lewin graduated in „Technology of Renewable Raw Materials“ from the University of Applied Sciences Hannover in 2001. In 2003, he joined JRS in Rosenberg, Germany, as a Project Manager for „Microencapsulation of Probiotic Bacteria.“ Over the years, Darek has held several key positions within the 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

Speaker

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).



Susanna Ralev
BASF, Germany

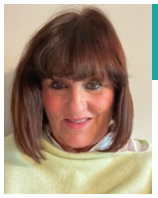
Susanna joint BASF in 2011. Since 2017, she has held the position of Global IT Validation Manager at operating division Care Chemicals. In this role she is responsible for the definition and implementation of global standards for Computerized System Validation (CSV) as well as for planning and execution of CSV activities. She was significantly involved in the creation of the BASF CSV Framework and is responsible for its implementation and further development.Susanna holds a degree in Business Administration with the emphasis on logistics and production management. Before joining BASF, she has worked for a consulting company for seven years. As a consultant and IT project manager Susanna has analyzed, designed, and implemented business processes and ERP system solutions in cooperation with various clients in the chemicals industry. The focus of her work was on the area of Supply Chain Planning.

Gabriele Reich
University of Heidelberg, Germany

Dr. Gabriele Reich is research group leader and academic director at the University of Heidelberg, Institute of Pharmacy and Molecular Biotechnology (IPMB), Dept. of Pharmaceutical Technology and Biopharmaceutics. She holds a pharmacy degree and a PhD in Pharmaceutical Technology from the University of Freiburg i. Br. and has more than 30 years experience in scientific research, academic teaching and international industrial consulting with a proven record of accomplishments in diverse areas of pharmaceutical technology, analytics, biopharmaceutics and polymer chemistry. Her research activities are focused on solid dosage forms including hard and soft capsules with special emphasis on QbD approaches and PAT solutions. Areas of expertise in soft capsule technology encompass gelatin and non-gelatin capsules. Current projects of her group comprise the development and in-depth characterization of innovative soft capsule products as well as smart polymer-based drug delivery systems with tailored release characteristics. She is a member of the APV focus group 'Solid oral dosage forms` and has been responsible for the organization of numerous international pharmaceutical conferences, seminars and workshops.

Leonie Schneider
Novartis, Switzerland

Leonie Schneider works as a Post-Doc in Technical Research and Development (TRD) at Novartis. She completed her studies in chemistry at the Philipps-University in Marburg (Germany) and obtained her PhD at the Karlsruhe Institute of Technology (KIT, Germany), where she focused on investigating the immune reaction of mast cells using synthetic DNA materials. In her current position at Novartis, she is working on alternative non-ionic surfactants in liquid NBE formulations to overcome the limitations of commonly used polysorbates. Today, she will provide insights into the surfactant's mode of action, the structure-function relationship, and the leading candidate for future formulations.



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.

Allan Whiston
QA Resolutions Ltd, UK

Allan Whiston is a professionally qualified Quality Practitioner (CQP) and Chartered Engineer with over 40 years' experience working within the Pharmaceutical Industry holding global positions before establishing a consultancy business in 2004 to support the pharmaceutical industry and it suppliers. Although broad based in experience, Allan has a particular interest in Supplier QA and Good Distribution Practices (GDP) within the Supply Chain. He is a past Chair and longstanding current member of the IPEC Europe GDP Committee.

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.

Christian Zeine
USP, Switzerland

Christian Zeine joined USP in 2019 as Senior Manager in the Scientific Affairs Group for the EMEA region, with a focus on Small Molecules, USP's General Chapters and Impurities. In his job, he collaborates with scientific experts and stakeholders and is responsible for protecting and growing USP's scientific reputation in the region and globally. Before joining USP, Christian worked for seventeen years in the field of pharmaceutical reference standards with a focus on impurities, and before that in the IVD (In Vitro Diagnostic) industry. His scientific expertise includes impurity testing, reference standards characterization and adjacent fields. Christian has published several articles and white papers on topics such as impurities, overview of (certified) reference materials and the use of reference standards in method development and validation. He earned his Ph.D. degree in Organosilicon Chemistry from the University of Muenster, Germany.

Registration by email apv@apv-mainz.de

MAKING SCIENCE WORK

Location

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mail
parkhotel.schoenbrunn@austria-trend.at

Date

Course no.: 3292
from 24 September 2024 09:00 h
to 25 September 2024 16:30 h

Registration fee

Early Bird Fee *(until 15 July 2024)*
Industry 1690 EUR[1]
Authority/University 845 EUR[1]

Regular Fee *(from 16 July 2024)*
Industry 1790 EUR[1]
Authority/University 895 EUR[1]

([1]plus VAT)

Coffee breaks, lunch, dinner and electronic proceedings included.

Registration

APV-Headquarters
Kurfürstenstraße 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

Austria Trend Parkhotel Schönbrunn
Hietzinger Hauptstraße 10
1130 Wien
Austria
Tel: +43 (1) 87 804-0
mail
parkhotel.schoenbrunn@austria-trend.at

We kindly ask you to book your hotel yourself. We have blocked a limited contingent on the special rate of 160,00 € incl. breakfast. Reservation via link (click here). Special rates available until 23 July 2024.

IPEC Europe Excipient Conference 2024 , 24 - 25 September 2024, Vienna, Austria, Course no. 3292

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.

☐ I also agree that APV and IPEC Europe 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.

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).

APV
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Title, first name, last name *

Company name *

Street/no. or P.O. box *

Location

Zip-code and city *

Phone

E-mail-address participant *

Order no. and/or billing address

☐ Pay via invoice

☐ pay via credit card (Visa, MasterCard, Amex)

Date * Signature *

* Mandatory

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

☐ New IPEC federation GDP Guideline

☐ Change Control Guideline

☐ How to provide regulatory information for excipients

Your registration fee also includes the participation in the Welcome Reception on, Monday, 23.09.2024 and the Social Event on the first conference day, Tuesday, 24.09.2024. Please let us know if you wish to attent:

Welcome Reception (23.09.2024)		Social Event (24.09.2024)	
☐ Yes	☐ No	☐ Yes	☐ No