IPEC Europe Excipient Conference

2020

17 - 18 September 2020
Frankfurt am Main • Germany
Course No. 3213

incl. Workshops:

Data Integrity – current experiences

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

Managing appropriate transport conditions for excipients – current experiences

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

IPEC Europe and APV are delighted to invite you to our 9th annual conference on pharmaceutical excipients.

The conference will focus on regulatory topics relating to pharmaceutical excipients and technology.

As part of the programme we will offer “workshops” to provide detailed practical information about current topics supporting industry to comply with regulatory requirements and other expectation. Three of these “workshops” will be held for 2 times in parallel to allow participants to attend 2 of the 3 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 regulatory environment. Topics will be data integrity, analytical method harmonisation and excipient transport.

The regulatory sessions will cover current hot topics like regulation in Europe and emerging countries, change control, data integrity and excipient information/data required for drug registration.

Since excipients are key parts of the formulation of medicines, we will open the second day with an outlook into the role of excipients to the year 2025 and beyond. Afterwards we will take the opportunity to listen to the new developments on excipients at EDQM and USP. Besides this we will highlight the role of excipients in the development of topical and intraoral drug delivery systems.

Continuous manufacturing presents a flexible approach to oral solid dosage form production and meets the industry’s demands for faster product development, reduced costs and increased manufacturing flexibility. We will learn the suitability and specific requirements of excipients for this new manufacturing process. Compendial specifications may not address all the physiochemical properties that can have an effect on manufacturability and final product quality.

The versatility and flexibility of 3D printing technique offers a large spectrum of advantages and will likely implement substantially improved medications in near future. Here, we will listen to a presentation of modified release tramadol printlets (3D printed tablets) with alcohol-resistant and abuse-deterrent properties prepared by direct powder extrusion three-dimensional (3D) printing.

The identification of contaminants on the surface of excipients used in the pharmaceutical industry with non-destructive techniques is a challenging procedure. Here we will present a modern technique based on Ultrasound Acoustic Atomic Force Microscope (UA-AFM).

We are looking forward to welcoming you in Frankfurt.
The primary goal of the conference is to highlight current hot topics in the field of pharmaceutical excipients. Take 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, we offer you to arrange your individual conference focus by choosing 2 of our three practical sessions 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:

- Excipient Regulation in Europe and Emerging Countries
- Change Control - What is different between pharma and excipient industry
- Excipient specific information and data required for drug product registration and supplier qualification
- The role of excipients in topical drug delivery
- 3 D printing
- Intracoral drug delivery
- Continuous manufacturing
- Data Integrity - current status of regulation
- Identification of contaminants in excipients using a non destructive technique

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 Board Member  
DuPont Nutrition & Health, Switzerland

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

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

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### Programme

**Wednesday, 16 September 2020**

On Wednesday, 16 September, at 19.00, participants are invited to a welcome reception at the Conference Hotel.

**Thursday, 17 September 2020**

09:00 to 18:00 h

**Registration**  
08:30 - 09:00 h

**Opening of Conference**

Dr. Amina Faham, DuPont Nutrition & Health, Switzerland  
Dr. Frank Milek, Aug. Hedinger GmbH & Co. KG, Germany  
Dr. Mahmud Yunis, BIOGRUND, Germany

**IPEC Federation presents:**

**Excipient Hot Topics**

**Introduction of IPEC Federation**

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

**Excipient Regulation in Latin America and India**

- Latin America and India - various excipient regulations are starting to be implemented  
- Excipients – sometimes treated in the same manner as APIs which is inappropriate  
- Regional Concepts for Excipient GMPs and Supply Chain Security  
- Issues with Excipient Stability and Expiration Dates  
- IPEC's initiatives to establish Industry partnerships and regulator relationships in these countries

David R. Schoneker, Black Diamond Regulatory Consulting, US

**Excipient Regulation in Europe**

- Pharmaceutical Excipients in the European regulatory landscape  
- General and specific references in the EU legislation  
- Risk based GMP requirements  
- Future regulatory topics

Frithjof Holtz, Chair IPEC Europe, Merck, Germany

**Change Control - What is different between pharma and excipient industry**

Dr. Johanna Eisele, Evonik Nutrition & Care GmbH, Germany

**Coffee Break and Table Top Exhibition**

**Excipient specific information and data required for drug product registration and supplier qualification**

N.N.

**Data Integrity - current status of regulation**

David Thompson, Clarity Compliance Solutions Ltd., United Kingdom

**Lunch Break and Table Top Exhibition**
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
- Appropriate alternative controls for Data integrity
Dr. Bernhard Appel, Roche, Germany
Dr. Ann Gulau, DuPont Nutrition & Biosciences, United States

Workshop 2
Internal analytical method harmonisation – an industry approach to safe testing resources
- Pharmacopeial 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, Hedinger Germany

Workshop 3
Managing appropriate transport conditions for excipients – current experiences
N.N., IPEC Europe GDP Committee

Coffee Break and Table Top Exhibition

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

Friday, 18 September 2020 08:45 to 16:45 h

EXCIPENTS IN DRUG DELIVERY

Excipients to the year 2025 – and beyond!
- Excipient understanding
- The impact of regulatory developments on excipients
- Possible future developments in the field.
Dr. R. Christian Moreton, FinnBrit Consulting, United States of America

New developments on excipients at EDQM
Dr. Dirk Leutner, European Pharmacopoeia Department (EPD), European Directorate for the Quality of Medicines and HealthCare, France

USP perspective on setting compendial specifications for excipient composition and impurities
- USP Background – USP and NF separate compendia; General Requirements
- Organic impurities- update on stim article, survey and comments received
- Elemental impurities- update on Roadmap and Compendial Notices
Dr. Galina Holloway, United States Pharmacopeia, United States of America

Coffee Break and Table Top Exhibition

Intraoral Drug Delivery: Three Ways to Prolong Mucosal Residence Time
- Mucoadhesive polymers and their use in mucoadhesive formulations
- Self-emulsifying drug delivery systems (SEDDS) for intraoral use
- Thiolated cyclodextrins – the next generation of mucoadhesives
Prof. Dr. Andreas Bernkop-Schnürch, University of Innsbruck, Austria

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 2020

Programme

Topical Drug Delivery and the Role of Excipients
- Particular aspects of excipients for topical formulations
- Direct and indirect contributions to efficacy
- How to efficiently choose from 500 approved excipients?
- Alterations of excipient functions upon integration to formulation matrix
- Analyzing & mitigating the impact of excipient variability

Dr. Michael Herbig, RaDes GmbH, Germany

Lunch Break and Table Top Exhibition

Continuous manufacturing of oral solid dosage forms – an excipient perspective
- Principles and examples of continuous manufacturing
- Excipient performance related properties
- Material attributes and process modelling
- Regulatory expectations

Dr. Liz Meehan, IPEC Board, AstraZeneca, United Kingdom

3D printing of opioid medicines with alcohol-resistant and abuse-deterrent properties
- Drug addiction and abuse affects millions of people worldwide and contributes to the global disease burden.
- Novel formulation strategies are needed to support efforts in minimizing the prevalence and risks of opioid abuse.
- This study reports, for the first time, the use of the recently developed ‘direct powder extrusion 3D printing technology’ to create alcohol-resistant and abuse-deterrent tablets with modified release properties, encouraging safer use of opioids.
- Low molecular weight hydroxypropyl cellulose in combination with high molecular weight polyethylene oxide are successfully used as binder and retarding polymer for the production Tramadol HCl printlets with the desired mechanical drug release properties.

Dr. Edmont Stoyanov, NISSO CHEMICAL EUROPE GmbH

Coffee Break and Table Top Exhibition

New techniques for understanding the surfaces of lactoses
- Innovative study on the characterization of the surface of lactoses intended for inhalation

Marie Charbaut/Nadège Prioul, Armor Pharma, France

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
- Meeting bags sponsored by
- Lanyards sponsored by
- 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 Valentina Marinkova, mv@apv-mainz.de.
Speaker

**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.

**Univ.-Prof. Dr. Andreas Bernkop-Schnurch**
University of Innsbruck, Austria

Andreas Bernkop-Schnurch was educated in pharmacy at the Institute of Pharmacy (M.Sc.) and in microbiology and genetics at the Institute of Microbiology and Genetics (D.Sc.), University of Vienna, finishing his doctorate in 1994. In 2003 he was appointed to a chair in pharmaceutical technology at the University of Innsbruck, Austria. From 2006 to 2013 he served as dean of the Faculty of Chemistry and Pharmacy at the University of Innsbruck. His research interest is in the area of mucoadhesive polymers, nanocarriers, peptide drug delivery and self-emulsifying drug delivery systems (SEDDS). He developed thiolated polymers (thiomes) and zeta-potential changing nanocarrier systems. Dr. Bernkop-Schnurch is author of over 450 research articles and reviews as well as editor and (co-)author of several books. He is the founder of Mucobiomer GmbH (now part of the Croma-Pharma Holding), Thiomatrix GmbH and Green River Polymers GmbH.

**Marie Charbaut**
Armor Pharma, France

Marie Charbaut studied chemistry at the engineering chemistry school of Toulouse (France). She obtained also a Master of Science degree in Chemistry with Biological Chemistry from the University of Kent (UK) and a specialization diploma in Drug Development and Analysis from the faculty of Pharmacy of Rennes (France). She started her career as a biochemist in Drug metabolism and Pharmacokinetic field at GSK in Ware (UK). Then she worked as an analytical scientist on Leachables and Extractables and as a powder formulation and optimization, and project management with companies including DuPont Nutrition & Health, Switzerland and an MBA from CUBS, UK. Prior to founding RaDes, he was Head of Pharmaceutical Development at Almiral Herman, Renbek, and held various positions in pre-formulation and formulation at Novartis, Basel. One focus of his work is to deepen the understanding of semi-solids formulations in terms of distribution processes and underlying thermodynamic principles to enable rationally designed products. Dr. Herbig is a member of the APV expert group for liquid and semisolid dosage forms and author of various publications in peer-reviewed journals as well as inventor of several granted formulation patents.

**Dr. Johanna Eisele**
Evonik Nutrition & Care GmbH, Germany

Johanna Eisele graduated in Veterinary Medicines from Giessen University, Germany in 1989. For her thesis she worked at E. Merck, Darmstadt, Germany. Veterinary Doctor Title was granted 1992. In October 1991 she started her carrier in the Institute of Toxicology, Hüls AG, which later became a part of Evonik. In 1995 she joined the Evonik Pharma Polymers business. Since 2002 Dr. Eisele is Head of Regulatory Affairs of Pharma Polymers, an Evonik business selling acrylic and biodegradable excipients (brands EUDRAGIT® and RESOMER®) for oral, dermal, and parenteral applications and for medical devices. Johanna Eisele represents Evonik Industries at the IPEC and is chairing IPEC Europe’s Quality and Regulatory Affairs Committee.

**Amina Faham, IPEC Europe Board Member**
DuPont Nutrition & Health, 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 Colcounor, 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 responsibility roles within R&D organization. As a result of the DowDuPont merger, Amina is leading the global application development and innovation of combined heritage FMC and Dow businesses since 2018. Her main responsibilities is to build, develop and lead high performing global teams 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 success.

**Dr. Ann Gulau**
DuPont Nutrition & Biosciences, United States

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.

**Dr. Michael Herbig**
RaDes GmbH, Germany

Dr. Michael Herbig is co-founder and managing director of RaDes GmbH, Hamburg, Germany, a development service provider for liquid and semi-solid formulations and the corresponding analytical methods. He has a PhD in pharmaceutical technology from ETH Zurich, Switzerland, and an MBA from CUBS, UK. Prior to founding RaDes, he was Head of Pharmaceutical Development at Almiral Herman, Renbek, and held various positions in pre-formulation and formulation at Novartis, Basel. One focus of his work is to deepen the understanding of semi-solid formulations in terms of distribution processes and underlying thermodynamic principles to enable rationally designed products. Dr. Herbig is a member of the APV expert group for liquid and semisolid dosage forms and author of various publications in peer-reviewed journals as well as inventor of several granted formulation patents.

**Dr. Galina Holloway**
United States Pharmacopeia, United States of America

Galina Holloway joined USP in 2006 and is currently a Senior Scientific Liaison responsible for development, modernization, and revision of Excipient Monographs and General Chapters. Before Dr. Holloway joined the Excipients group, she was a senior group leader at USP Research and Development Laboratory where she led a group of highly qualified scientists in development and validation of analytical procedures for drug substances, drug products, food ingredients, excipients and dietary supplements. Dr. Holloway has more than 25 years’ experience as an analytical chemist both in the US and Russia. She has headed a research laboratory on water quality for the Russian Academy of Sciences, been a senior analytical chemist for a major international pharmaceutical company, and been laboratory director of an independent tobacco products testing laboratory. Dr. Holloway holds a Ph.D. in Chemical Enzymology and a M.S. in Organic Chemistry from Moscow State University, Russia.

**Dr. Frithjof Holtz**
IPEC Europe Chair
Merck KGaA, Germany

Frithjof Holtz is a biologist and is working for more than 30 years with Merck KGaA, Darmstadt, Germany, having years of experience in quality assurance and regulatory affairs. Besides experience in chemical manufacturing (excipients/APIs) he also has working experience in quality assurance for drug products (sterile/non-sterile). Furthermore, Frithjof is working for more than 15 years in Regulatory Affairs (CMC) for pharmaceutical starting materials and consumables and their regulatory needs for their use in sterile/non-sterile drug product manufacturing and registration. Currently he is responsible for Regulatory Intelligence for Merck Life Science. Furthermore Frithjof Holtz has many years of experience in working in industry associations as in Rv360, ARIC, EFCC, PDA and IPEC.
As an experienced material scientist, Liz joined AstraZeneca in 2003 as an Associate Principal Scientist specialising in Polymer Science, focused on polymeric excipients used across a wide range of formulation platforms. Since 2014, in her broader role as a Principal Scientist in Material Attributes and Product Performance, she has responsibility for the development of materials control strategies for oral and parenteral drug product development and commercialisation, including both APIs and excipients. Liz has served as a main board member of IPEC Europe for the last 6 years.

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 manufacturing. 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 the Executive Committee serving as the Vice Chair for Science and Regulatory Policy, where he is actively involved with the development of Regulatory, Safety, Excipient GMP and Supplier Qualification related guidelines to improve Excipient Acceptability, Safety and Global Supply Chain Security. Mr. Schoneker also Chairs IPEC's Q&D/Product Development Committee, Composition Committee and IID Working Group and is a member of the Board of Directors of the IPEC Foundation. He is the Global Expansion Coordinator for the IPEC Federation and has been critically involved in the development of many of the IPEC regional groups and partnerships around the world.

Dr. Edmont Stoyanov graduated Pharmacy at the Medical University in Sofia, Bulgaria. He holds his Ph.D in the field of Organic and Medicinal Chemistry focused on the synthesis design, isolation and spectral analysis of novel biologically active substances. Dr. Stoyanov has over 15 years of experience in the excipient business leading technical teams at JRS Pharma, EIP/Ashland and NISSO. He published over 80 papers and posters in the field of organic and medicinal chemistry and pharmaceutical technology. Edmont holds several patents on novel application of solid dosage and co-processed excipients. Dr. Stoyanov joined NISSO in September 2016 as Global Technical Director.

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.
## IPEC Europe Excipient Conference, 17-18 September 2020, Frankfurt am Main, Germany, Course no. 3213

### 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/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. 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).

### Hotel reservation

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

Participants should make their own hotel reservation. Deadline for special conference rate: 03 September 2020. Please use the booking link on our homepage: https://www.apv-mainz.de/en/seminare/events/event/seminar/3213

### Seminar registration

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

### Location

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<th>Scandic Frankfurt Museumsufer</th>
<th>Wilhelm-Leuschner-Straße 44</th>
<th>60329 Frankfurt am Main</th>
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<td>Tel: +49 69 9074 59 0</td>
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### Date

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<tr>
<th>Course no. 3213 from 17 September 2020 to 18 September 2020</th>
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<td>09:00 h Coffee breaks, lunch, dinner and electronic proceedings included.</td>
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### Registration fee

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<th>Early Bird Fee (until 30 June 2020)</th>
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<td>Industry Authority/University</td>
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<td>1490 EUR (1 plus VAT)</td>
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### 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

Scandic Frankfurt Museumsufer  
Wilhelm-Leuschner-Straße 44  
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https://www.apv-mainz.de/en/seminare/events/event/seminar/3213