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
- Intraroral 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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### Objectives

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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

**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 and Emerging Countries**

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**

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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 pharma 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)

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.
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

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

We are offering a tabletop for 995 Euro (excl. VAT) + one mandatory full conference registration.

Space is limited, and applications will be dealt with on a “first come, first served” basis.

A tabletop includes:
- one table
- two chairs
- electricity
- power supplies

For 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.
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.

Andreas Bernkop-Schnürch 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 (thiomers) and zeta-potential changing nanocarrier systems. Dr. Bernkop-Schnürch 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 Cioma-Pharma Holding), Thiomatrix GmbH and Green River Polymers GmbH.

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 career as a biocynist in Drug metabolism and Pharmacokinetic field at GSK, Ware (UK). Then she worked as an analytical scientist on Leachables and Extractables and as a powder formulation scientist on Dry Powder Inhalers at Apta Pharma, supplier of drug delivery systems. Currently she is working at Armor Pharma, provider of pharmaceutical grade lactose as a Technical Support and Project Leader. Her main fields of expertise are the applications of lactose for Oral Solid Dosage Forms and customer/ universities technical support.

Dr. 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, Ware (UK). Then she worked as an analytical scientist on Leachables and Extractables and as a powder formulation scientist on Dry Powder Inhalers at Apta Pharma, supplier of drug delivery systems. Currently she is working at Armor Pharma, provider of pharmaceutical grade lactose as a Technical Support and Project Leader. Her main fields of expertise are the applications of lactose for Oral Solid Dosage Forms and customers/universities technical support.

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 OUBS, UK. Prior to founding RaDes, he was Head of Pharmaceutical Development at Almiral Hermal, Reinbek, 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 semi-solid dosage forms and author of various publications in peer-reviewed journals as inventor of several granted formulation patents.

Dr. 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 Coloclon, 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 respon-

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.

Frithjof Holtz, IPEC Europe Chair
Merck KGaA, Germany

Frithjof Holtz is a biologist working for 30 years for Merck KGaA, Darmstadt, Germany. He has experience in operations, QA and had over the last 15 years several positions in Regulatory Management (CMC). Frithjof Holtz has been working with a number of industry associations (e.g. Rx-360, APIC, EFCG, PDA, IPEC) and is as Senior Expert responsible for Regulatory Intelligence at Merck KGaA, Darmstadt, Germany, Life Science.
IPEC Europe Excipient Conference 2020

Speaker

Dr. Dirk Leutner
EDQM, France

Dr. Dirk Leutner is head of the department “Pharmaceutical Technology” in the pharmacopoeia department of the EDQM.

Dr. Liz Meehan
AstraZeneca, United Kingdom

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

Dr. Frank Milek is an industrial pharmacist. He is PhD pharmacist graduated at the Universities of Würzburg and Tübingen (Germany). He is working for more than 20 years inpharmaceutical excipient industries, especially in the field of supply chain, distribution and manufacture. Frank is an expert for regulatory affairs, quality system standards and GMP/GDP compliance. He is a registered Qualified Person according to EU regulation and responsible at Aug. Hedinger GmbH & Co. KG, a specialised excipient supplier in Germany for Quality, RA and GMPs. Frank Milek is member of different committees of industrial trade associations (Fecc, Ipec, BAH and APV). He is currently President of IPEC Federation, Chair IPEC Europe GDP Committee and vice-chair of the International Pharmaceutical Excipients Council Europe (IPEC Europe).

Dr. R. Christian Moreton
FinnBrit Consulting, United States of America

Dr. Moreton is a partner at FinnBrit Consulting, providing consulting and advisory services in formulation and process design, development and scale up, and in aspects of excipient development. Prior to FinnBrit Consulting, he spent 30 years working in industry, mainly as a pharmaceutical formulation scientist working in large and small innovator companies, and in generic companies. Dr. Moreton has also worked in QA, QC and Regulatory Affairs for an excipient and drug delivery company. He is a past Chair of IPEC-Americas and is currently a member 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 Co-Chairs IPEC’s QbD/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
NISSO CHEMICAL EUROPE GmbH, Germany

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, NYSIS A/S 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, 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 GSp procedures and processes for five years.

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

Tanja Natterer studied pharmacy at the University of Tübingen and is a specialist pharmacist for pharmaceutical analysis. She is working in the pharmaceutical quality control in the GMP Laboratory Hedinger, Stuttgart (Germany) since 2011. In her current function as head of quality control and Qualified Person acc. to §14 AMG she is responsible for multicompound compliance testing of pharmaceutical excipients.
Seminar registration by fax +49 6131 97 69 69
or by e-mail apv@apv-mainz.de

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Tel.: +49 69 9074 59 0
Fax: +49 69 907459 335

Registration fee
Early Bird Fee (until 30 June 2020)
Industry: 1490 EUR\(^1\)
Authority/University: 745 EUR\(^1\)
Regular Fee (from 01 July 2020)
Industry: 1590 EUR\(^1\)
Authority/University: 795 EUR\(^1\)
(plus VAT)

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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/seminar/events/event/seminar/3213

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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

1 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.
2 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).

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Welcome Reception (16.09.2020)

Social event (17.09.2020)

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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):

1 Data integrity – current experiences
2 Internal analytical method harmonisation – an industry approach to safe testing resources
3 Managing appropriate transport conditions for excipients – current experiences

Your registration fee also includes the participation in the Welcome Reception on Wednesday, 16.09.2020 and the Social Event on the first conference day, 17.09.2021.

Please let us know if you wish to attend:

Welcome Reception (16.09.2020)  
Social event (17.09.2020)

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Yes  
No

Yes  
No