IPEC Europe Excipient Conference

2021

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

22 - 23 September 2021

LIVE ONLINE

Course No. 3232

ONLINE Conference

IPEC EUROPE

APV

IPEC Europe Excipient Conference 2021

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.

The regulatory sessions will cover current hot topics like regulation in Europe and emerging countries, the news from EDQM and USP as well as an outlook into the role of excipients to the year 2025 and beyond. Since excipients are key parts of the formulation of medicines, we will open the second day with presentation on the role of excipients in the development of intraoral and topical 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.

We are looking forward to welcoming you.

Dr. Amina Faham
IPEC Europe Board Member

Dr. Frank Milek
IPEC Europe Vice-Chair

Dr. Mahmud Yunis
IPEC Europe Board Member

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Objectives

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.

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

- Excipient Regulation in Europe
- New developments on excipients at EDQM
- USP perspective on setting compendial specifications for excipient composition and impurities
- Excipient Regulation in Europe and Emerging Countries
- Intraoral drug delivery
- The role of excipients in topical drug delivery
- 3 D printing
- Continuous manufacturing

Target Group

This conference is intended for professionals working in:

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

The seminar is also intended for members of regulatory authorities and purchasing departments.

Programme Committee

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

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

Dr. Mahmud Yunis
IPEC Europe Board Member
BIOGRUND, Germany

Sponsoring Options

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 sponsoring package for 990 Euro (excl. VAT) including a virtual stand and one full conference registration.
For detailed information about the sponsoring options, please contact Katrin Kälkert, kk@apv-mainz.de.

Programme

Wednesday, 22 September 2021 13:00 to 18:00 h

Exhibition Area and Networking 13:00-13:30 h

Opening of Conference 13:30 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

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

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

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, US

Exhibition Area and Networking

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, US

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

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Programme

Thursday, 23 September 2021 13:00 to 18:00 h

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

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

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, UK

Exhibition Area and Networking

3D printing of opioid medicines with alcohol-resistant and abuse-deterrent properties

- Drug addiction and abuse affects millions of people world wide 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 combina tion with high molecular weight polyethylene oxide are successfully used as binder and retarding polymer for the production Tramadol HCl printlets with the desired mecha nical drug release properties.

Dr. Edmont Stoyanov, NISSO CHEMICAL EUROPE GmbH, Germany

Closing remarks

Programme is subject to change

Speaker

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

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 Croma-Pharma Holding), Thiomatrix GmbH and Green River Polymers GmbH.

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

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

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 Almirall 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 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, US

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

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Speaker

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 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 has also 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 Rx-360, APIC, EFCG, PDA and IPEC.

Dr. Dirk Leutner
EDQM, France

"Dirk Leutner is head of the Pharmaceutical Technology Section in the European Pharmacopoeia Department of the EDQM. He is pharmacist with a PhD in Pharmaceutical Technology and experience in the pharmaceutical industry in development of generics and as head of production. In 2013, he joined the EDQM as scientific program manager and worked for groups of experts in the field of medicinal products monographs, chemical substances, spectroscopic methods including PAT and the European Paediatric Formulary. Since 2017 he manages the work on excipients, dosage form monographs and testing, packaging material, PAT and the European Paediatric Formulary. He further coordinates the pharmacopoeial harmonisation (e.g. PDG) activities within the European Pharmacopoeia Department.

Dr. Liz Meehan
AstraZeneca, UK

As an experienced material scientist, Liz joined Astra Zeneca in 2003 as an Associate Principal Scientist specialising in Polymer Science, focussed 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

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 a registered Qualified Person according to EU regulation and responsible for Quality, RA and GMPs at Aug. Hedinger GmbH & Co. KG, a specialised excipient supplier in Germany. Frank Milek is member of different committees of industrial trade associations (FECC, IPEC, BAH and APV). He is currently and vice chair of the International Pharmaceutical Excipients Council Europe (IPEC Europe) as well as chairman of the Good Trade and Distribution Practice Committee of IPEC Europe and president of IPEC Federation.

Dr. R. Christian Moreton
FinnBrit Consulting, US

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 IPEC-Americas QbD and Excipient Composition Committee and GMP Committee. Dr. Moreton is also on the faculty of Manchester University in the UK on their PIAT distance learning program covering oral solid dosage forms. Dr Moreton holds a B.Pharm. degree (Nottingham University, UK), a M.Sc in pharmaceutical analysis (University of Strathclyde UK) and a Ph.D in Pharmaceutics (University of Wales College of Cardiff; now Cardiff University, UK).

David R. Schoneker
Black Diamond Regulatory Consulting, 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. He is also an Adjunct Professor at Temple University's School of Pharmacy in their RA/QA Master's Program where he teaches 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. Mr. Schoneker was the Chairman of IPEC-Americas during the period 2007-2009 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, ISP/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, IPEC Europe Board Member
BIOGRUND, Germany

Dr. Mahmud Yunis has been working for 15 years at BIOGRUND in several positions. In his current function as Technical Director, he is responsible for preparing and implementing global strategic regulatory plan for BIOGRUND products and the strategic development of the Quality, Production and R&D department. He has a PhD degree in Analytical Chemistry from University of Muenster, Germany. Before joining BIOGRUND he worked for a consulting company on the area of GxP procedures and processes for five years.

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

Date

Course no. 3232
from 22 September 2021 13:00 h
to 23 September 2021 18:00 h

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Registration fee

Early Bird Fee *(until 31 July 2021)*
Industry 750 EUR[1]
Authority/University 375 EUR[1]

Regular Fee *(from 01 August 2021)*
Industry 840 EUR[1]
Authority/University 420 EUR[1]

Sponsoring package 990 EUR[1]
(incl. 1 virtual stand and 1 full conference ticket)

([1]plus VAT)

Registration

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

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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

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