IPEC Europe Excipient Conference

2019

– An update on regulatory developments and their application –

24 - 25 September 2019

Vienna ▪ Austria

Course No. 3203

incl. Pre-Conference

Practical Sessions

Achieving compliance for Excipients using IPEC Guidelines

- IPEC Co-processed Excipient Guide for Pharmaceutical Excipients
- IPEC Good Distribution Practices Guide for Pharmaceutical Excipients
- IPEC Technically Unavoidable Particle Profile (TUPP) Guide

IPEC EUROPE

APV

IPEC Europe Excipient Conference 2019

Dear Colleagues,

IPEC Europe and APV are delighted to invite you to our 8th annual conference on pharmaceutical excipients.

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

As part of the programme we will offer "practical sessions" to provide detailed information about current IPEC Guidelines supporting industry to comply with regulatory requirements and other expectations .Three of these "practical sessions" will be held for 2 times in parallel to allow participants to attend 2 of the 3 sessions. These sessions will focus on the content of the IPEC Guidelines and provide practical examples to facilitate implementation in a company's quality system. Participants will learn how to use the guides in daily work and can discuss with the speakers about their personal experience.

We will open the technical and scientific session of the conference with two compendial topics presented by EDQM and USP.

The remaining of the session will focus on the application of the excipients and the new findings in key areas such as pediatrics, solid dispersions as well as taste masking.
We will also have an opportunity to hear an overview on the evolving landscape of the pharmaceutical industry.

Last but not least networking and exchange of information is a key feature of the event and table-top exhibitions aligned to the conference will encourage communication between suppliers and users.

We are looking forward to welcoming you in Vienna.

Dr. Amina Faham
IPEC Europe Board Member

Dr. Frank Milek
IPEC Europe Vice-Chair

Dr. Mahmud Yunis
IPEC Europe Board Member

IPEC Europe Excipient Conference 2019

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.
This year again, we offer you to arrange your individual conference focus by choosing 2 of our three practical sessions on the first day.
You will learn how to achieve compliance for excipients by using the IPEC Guides for:

- Co-processed Excipients
- GDP for Pharmaceutical Excipients and
- Technically Unavoidable Particle Profile (TUPP)

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

- The IPEC-PQG Good Manufacturing Practices Guide
- The IPEC Significant Change Guide
- Comparison of GMP Standards
- The use of harmonised alternative methods:
  - The EDQM view
  - The USP view
- The Pharmaceutical excipient market today
- The role of excipients in:
  - Paediatric formulations and
  - Amorphous solid dispersions
- Drug- and market-related implications on formulation and manufacturing of amorphous solid dispersions
- Taste-masking approaches for bad tasting drugs

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
DuPont Nutrition & Health, Switzerland

Dr. Frank Milek
Vice-Chair IPEC Europe
Hedinger, Germany

Dr. Mahmud Yunis
IPEC Europe Board Member
BIOGRUND, Germany

Programme

Tuesday, 24 September 2019 08:30 to 13:30 h

Registration

Pre-Conference Practical Sessions:
Achieving compliance for Excipients using IPEC Guidelines "What it is and how to do"
(Practical sessions 1-3 will run in parallel two times)

IPEC Federation presents:
GxP for Excipients - The IPEC Way

Session 1
IPEC Co-processed Excipient Guide for Pharmaceutical Excipients
Content of the guide and it's practical implementation
Brian Carlin
DFE Pharma, United States of America

Session 2
IPEC Good Distribution Practices Guide for Pharmaceutical Excipients

- Introduction to the WHO and IPEC GD principles for excipient
- Detailed content of the guide
- Practical examples for implementation into a quality system

Dr. Frank Milek
Hedinger, Germany

Session 3
IPEC Technically Unavoidable Particle Profile (TUPP) Guide

- Introduction to the guide
- Detailed Content of the guide
- Practical examples of its implementation

Darek Lewin
JRS Pharma GmbH + Co KG, Germany

Coffee Break and Table Top Exhibition

Repetition of Practical Sessions 1-3
(Practical sessions 1-3 will run in parallel two times)

Review of practical sessions

Lunch Break and Table Top Exhibition

IPEC Europe Excipient Conference 2019

Programme

Tuesday, 24 September 2019 13:30 to 18:00 h

Opening of Conference
Dr. Amina Faham, DuPont Nutrition & Health, Switzerland
Dr. Frank Milek, Hedinger, Germany
Dr. Mahmud Yunis, BIOGRUND, Germany

Introduction of IPEC Federation
Dr. Frank Milek
Hedinger, Germany

Practical Sessions

IPEC PQG Good Manufacturing Practice Guide for Excipients
Content of the guide and it's practical implementation
- There is more than one way to compliance with this Guide
- Dare to choose the best way for your way of working and
- Explain your decisions conclusively

Astrid Stockrahm-Uhling
DFE Pharma, Germany

Change Control – The IPEC Significant Change Guide for Pharmaceutical Excipients
- Overview on the IPEC Significant Change Guide for Pharmaceutical Excipients
- How to integrate the IPEC Guide in an excipient quality management system
- Examples for the assessment of the significance of changes
- Integration of the IPEC guide into quality agreements with customers and suppliers

Dr. Philipp Hoch
Hedinger, Germany

Coffee Break and Table Top Exhibition

Comparison of GMP Standards - What is the difference?
- Medicinal product GMP
- API GMP
- Excipient GMP
- Food and cosmetic GMP
- Practical examples of differences at a supplier of excipients and APIs

Dr. Norbert Waldöfner
Blue Inspection Body GmbH, Germany
Dr. Frank Milek
Hedinger, Germany

Social programme

We are delighted to invite you to join us for dinner and a sight-seeing tour. Come and meet colleagues and specialists in the field of excipients around the world in an enjoyable and relaxed atmosphere.

Wednesday, 25 September 2019 09:00 to 16:30 h

What does compliance with the European Pharmacopoeia mean?
- Ph. Eur. concepts and requirements
- Compliance and waivers
- Use of alternatives methods and flexibility
- Place of the Ph. Eur. in the Regulatory environment
- International Harmonisation (PDG)
- Challenges of compliance for excipients
- Update on Ph. Eur. excipient monographs

Anne Garnier-Poidevin
European Directorate for the Quality of Medicines and Healthcare, France

USP's views on the use of Alternative and Harmonized Methods and Procedures
- Introduction to USP and its General Notices
- Conformance to standards and Applicability of Standards to excipients
- Validation of USP compendial procedures
- Update on USP excipient monographs including excipients on the PDG list

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

Coffee Break and Table Top Exhibition

Pharmaceutical excipients market today: A rapidly evolving landscape...
Dr. Amina Faham
DuPont Nutrition & Health, Switzerland

The Role of Excipients in Paediatric Formulations
- Toxicity in children and adolescents
- Excipients of concern
- PDCO comments on excipients
- STEP database

Prof. Dr. Jörg Breitkreutz
University of Duesseldorf, Germany

Lunch Break and Table Top Exhibition

The Role of Excipients in Amorphous Solid Dispersions
- Thermodynamic stability of ASDs
- Influence of polymeric excipients on the long-term stability of ASDs
- Role of excipients on the water sorption and ASD stability at humid conditions
- Role of excipients on the hydrate formation in ASDs

Prof. Dr. Gabriele Sadowski
TU Dortmund University, Germany

IPEC Europe Excipient Conference 2019

Programme

Drug- and market-related implications on formulation and manufacturing of amorphous solid dispersions

- Overview on excipients used in amorphous solid dispersions
- Drug-related criteria to select the most suitable excipients and formulation design
- Market-related implications on the right choice of enabling technology
- Regulatory guidance on amorphous solid dispersions
- Functionality-related characteristics of excipients required for their optimal functionality

Dr. Jessica Müller-Albers
Evonik, Germany

Coffee Break and Table Top Exhibition

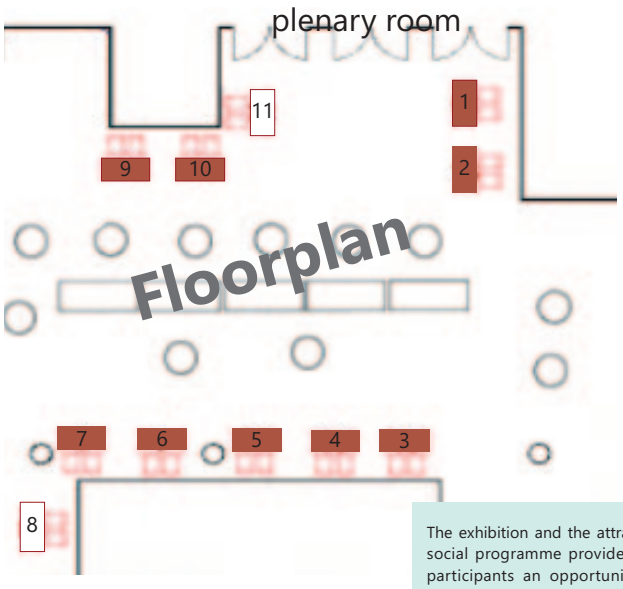
Overcoming the yuck factor: effective taste-masking approaches for bad tasting drugs

- Insight into using neutral tasting lipid excipients for APIs with poor gustatory properties
- Excipient physical-chemical properties and "proof of concept"
- Encapsulation of API by hot melt coating
- Coating by high shear granulation
- Approaches to rapidly measure efficacy in vitro and qualification by human taste panel

Ana Carolina Gutierrez
Gattefossé, France

Closing remarks

Programme is subject to change



The exhibition and the attractive social programme provides the participants an opportunity to meet up with the other visitors.

IPEC EUROPE

ZERION # 1
BIOGRUND # 2
Excipia. # 3
OKYA # 4
eurofins # 5
HEDINGER # 6
BRENNTAG # 7
BASF # 9
JRS PHARMA FAMILY # 10

Table Top Exhibition/Sponsoring

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

BIOGRUND
Colorcon

For detailed information about exhibiting and the different sponsoring options, please go to our website www.apv-mainz.de or contact Heide Zweyer, hz@apv-mainz.de.

IPEC Europe Excipient Conference 2019

Speaker

Prof. Dr. Jörg Breitkreutz
University of Duesseldorf, Germany

Jörg Breitkreutz is a pharmacist by training and finished his PhD in 1996 at the Institute for Pharmaceutical Technology and Biopharmaceutics in Münster under supervision of Prof. Gröning. From 1996 to 1997 he joined Thiemann Arzneimittel GmbH in Waltrop, Germany, and from 1997 to 2004 the University of Münster to work on his habilitation on paediatric drug formulations. In 2004 he became professor for pharmaceutical technology at the Heinrich-Heine-University in Düsseldorf, Germany. Since 2010 he is the president of the International Association of Pharmaceutical Technology (APV). His research focuses on paediatric drug formulations, orphan drugs and process analytical technologies.

Dr. Brian Carlin
DFE Pharma, United States of America

Brian Carlin is Director QbD/Regulatory at DFE Pharma. He previously worked at FMC, SmithKline Beecham & Richardson Vicks. He is a Fellow of the Royal Pharmaceutical Society, and holds honorary Professorships at DeMontfort University and University of Maryland. He is the recipient of the 2014 IPEC One World Award for Regulatory Excellence, and the 2012 IPEC Foundation Award for Industry Research Achievement. He is the immediate past chair of the IPEC Americas QbD and Excipient Composition Committees. He has a doctorate in Interfacial Rheology from London University, and a degree in Pharmacy from the University of Aston in Birmingham.

Dr. Amina Faham
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 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.

Ana Carolina Gutierrez
Gattefossé, France

Ana's academic background is in Industrial Pharmaceutical Sciences. She was Assistant Professor in the Pharmacy School at the Metropolitan Autonomous University of Mexico and gained considerable industrial experience whilst at Bristol Myers Squibb where she worked in manufacturing and technology transfer for solid oral dosage forms. At Gattefossé Ana is responsible for providing technical support and delivering seminars and training programmes in Europe and South-America and due to her professional background, she is particularly focussed on formulation and production processes for solid oral dosage forms

Dr. Philipp Hoch
Hedinger, Germany

Dr. Philipp Hoch graduated in Pharmacy in 2010 at the University of Marburg. He finished his PhD thesis in 2014 in the field of RNA biochemistry, in particular RNA-mediated regulation of transcription. Thereafter he continued his studies in this field as a post-doctoral researcher until 2016. In 2016 he joined Aug. Hedinger GmbH & Co. KG, where he is now responsible for regulatory affairs, quality assurance and especially change control management.

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.

Darek Lewin
J. Rettenmaier & Söhne GmbH + Co KG, Germany

Darek Lewin graduated in "Technology of Renewable Raw Materials" in 2001 at the University of Applied Sciences Hannover. In 2003, he was employed as Project Manager for "Microencapsulation of Probiotic Bacteria" at J. Rettenmaier & Söhne GmbH & Co KG, Rosenberg, Germany, a world-wide, dynamic leader in the fiber industry. JRS provides with their fiber products solutions for various applications and chemical processes for almost every field of daily life, i.e. for pharmaceutical and food applications, or for technical and industrial use. From 2004 to 2006, he was responsible as the Food and Feed Safety Manager and then as Corporate Quality Manager for JRS Pharma GmbH & Co KG. JRS Pharma is one of the leading excipient manufacturer with a wide portfolio of functional excipients. Since 2007, Darek Lewin is the Head of Quality for the JRS Group with production plants in Europe, USA, India, China and Mexico. As a member company of IPEC, Darek knows the current IPEC guidelines from their development and has a deep knowledge and know-how about their implementation at a manufacturer.

IPEC Europe Excipient Conference 2019

Speaker

Dr. Frank Milek
Hedinger, 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 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 chairman of the Good Trade and Distribution Practice Committee of the European Association of Chemical Distributors (FECC) and vice-chair of the International Pharmaceutical Excipients Council Europe (IPEC Europe).

Dr. Jessica Müller-Albers
Evonik, Germany

Dr. Jessica Müller-Albers studied pharmacy and obtained a Ph.D. in Pharmaceutical Technology from the University of Düsseldorf with research focusing on solubility enhancement of poorly soluble drugs. After graduating, Jessica started her pharmaceutical career with a CMO as a Project Manager in formulation development for orals and semi-solids. In 2010 she joined Evonik Nutrition & Care GmbH where she held a range of technical positions comprising of orals, nutraceuticals and oral and parenteral drug delivery technologies for small molecules and biopharmaceuticals. Before taking over her current business role, she was the scientific communication manager for advanced food ingredients, amino acids and cell culture. Since last year, Jessica is the Global Strategic Marketing Director of Evonik's Oral Drug Delivery Solutions business. In this role, she is technically responsible for the oral drug delivery portfolio with the specialization in bioavailability enhancement and drug delivery.

Anne Garnier-Poidevin
EDQM, France

Mrs Anne Garnier-Poidevin graduated in Pharmacy in 2005 from the University of Strasbourg and obtained a Master's degree in European Community Law and Pharmaceutical Regulation in 2006.
She joined the European Pharmacopoeia Department of the European Directorate for the Quality of Medicines & HealthCare (EDQM) in 2005, where she is currently scientific program manager in charge of groups of experts 13H (Fatty oils and derivatives, polymers), EXP (Excipient performance) and HMM (Homoeopathic Manufacturing Methods). She is also in charge of coordinative work in the framework of International harmonisation within PDG. From 2005 to 2015, she was involved in expert groups dealing with chemically defined active substances.

Prof. Dr. Gabriele Sadowski
TU Dortmund University, Germany

Prof. Dr. Gabriele Sadowski received her Ph.D. in Physical Chemistry and became full Professor for Thermodynamics in 2001 at TU Dortmund University. She is author of about 200 scientific publications in the field of chemical, biochemical and pharmaceutical engineering. The main focus of her research is studying thermodynamic properties of complex systems with particular emphasis to those containing pharmaceutical molecules. Her group developed the currently worldwide most-used thermodynamic model PC-SAFT which was published in 2001. She received numerous awards for her work, the most-prestigious one being the Gottfried Wilhelm Leibniz Award of the German Science Foundation in 2011.

Astrid Stockrahm-Uhling
DFE Pharma, Germany

Astrid Stockrahm-Uhling is Global QA Specialist at DFE Pharma. In 2007 she joined the excipient manufacturer DFE Pharma with more than 10 years of experience in pharmaceutical business, covering the range from research & development to storage & distribution of medicines as well as computer validation. At DFE Pharma she took up the position as QA Manager with overall responsibility for all QA and Regulatory activities worldwide. Since 2014 she serves as Internal Advisor for GMP compliance and is the company's official representative in IPEC activities. For IPEC, Astrid is currently leading the GMP Guide revision team.

Dr. Norbert Waldöfner
Blue Inspection Body GmbH, Germany

Dr. Norbert Waldöfner is a chemist with 17 years of experience in industry (covering product development, manufacturing of sterile injection solutions for cancer therapy, quality control, quality management and auditing). He is a qualified GMP lead auditor for blue inspection body since 2011 with about 30-40 audits performed each year (APIs, excipients, medicinal products and related scopes, such as e.g. packaging materials, GDP etc.). Dr. Waldöfner is involved in audit planning, project management and quality management in the framework of an accredited quality management system according to the requirements of ISO 17020 and ISO 17021.

Dr. Mahmud Yunis
BIOGRUND, Germany

Dr. Mahmud Yunis has been working for 13 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.

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

Location

Austria Trend Hotel Savoyen Vienna
Rennweg 16
1030 Vienna
Tel.:+43 1 20633
E-Mail:www.austria-trend.at

Date

Course no. 3203
from 24 September 2019 08:30 h
to 25 September 2019 16:30 h

Registration fee

Industry 1590 EUR[1]
Authority/University 795 EUR[1]
([1]plus VAT)

Coffee breaks, lunch, dinner and electronic proceedings included.

Registration

APV-Geschäftsstelle
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 Hotel Savoyen Vienna
Rennweg 16
1030 Vienna
Tel.:+43 1 20633
E-Mail:www.austria-trend.at

Participants should make their own hotel reservation referring to the APV seminar. Deadline for special conference rate: 26 August 2019. Special rate: Single room incl. breakfast from 150,00 € per night.

IPEC Europe Excipient Conference, 24 - 25 September 2019, Vienna, Austria, Course no. 3203

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 APVI/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).

APV GmbH
Kurfürstenstraße 59
55118 Mainz/Germany
www.apv-mainz.de

Phone: 0049 6131 97 69 0
Fax: 0049 6131 97 69 69
E-mail: apv@apv-mainz.de

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Date * Signature *

* Mandatory

Please select 2 of the following Practical Sessions (please tick only 2)

☐ IPEC Co-processed excipient Guide

☐ IPEC Good Distribution Practices Guide for Pharmaceutical Excipients

☐ IPEC Technically Unavoidable Particle Profile (TUPP) Guide

Your registration fee also includes the participation in the Social Event.
Please let us know if you wish to attent:

☐ Yes

☐ No