APV/IPEC Europe Excipient Conference 2017

– An update on regulatory developments and their application

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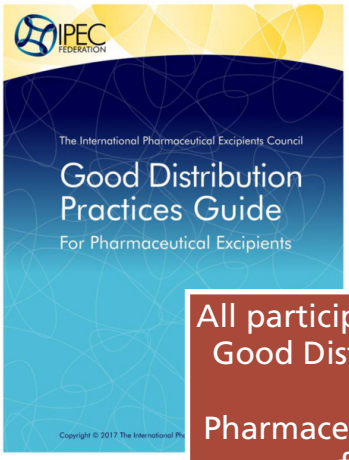
19 - 20 September 2017

Berlin · Germany

Course No. 3177



All participants receive the Good Distribution Guide for Pharmaceutical Excipients for free

including 3 parallel workshops

Data Integrity – How to apply in excipient manufacture and supply chain

Quality Agreements – A simple story!?

Stability testing of Excipients – The IPEC Excipient Stability Program Guide (2010)

IPEC EUROPE 25 Years 1992-2017

APV

APV/IPEC Europe Excipient Conference 2017

– An update on regulatory developments and their application

Dear Colleagues,

IPEC Europe and APV are delighted to invite you to our 6th annual conference on pharmaceutical excipients.

The conference will focus on "hot topics" in the area of excipient regulation and technology. In contrast to the market for finished drugs and active pharmaceutical ingredients the market for excipients is extremely difficult to quantify. For the first time one lecture of the conference will provide an overview of the global excipients market with the focus on oral solid dosage forms.

As part of the programme we will offer three parallel workshops to provide practical, hands-on insight and discussion on pressing regulatory topics, with a view to developing joint solutions. These workshops will focus on data integrity in excipient manufacture and supply chain, quality agreements and stability testing of excipients.

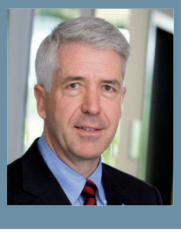
Beyond that the regulatory session will highlight the multifaceted challenges to ensure excipient compliance such as multi-compendial compliance of excipients, excipient packaging systems and excipient supply chain. How to verify that excipient suppliers work in compliance with the regulations and the transport of excipients will be reviewed too.

The technical and scientific part of the conference will deal with important excipient functionalities such as diluents for direct compression, the role of excipients in inhalation drugs and transdermal drug delivery. Further topics will be the requirements of excipients for continuous manufacturing processes and the impact that excipient grades have on the bioequivalence of generic drugs.

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 Berlin.

Frank Milek
Vice-Chair IPEC Europe



Hubertus Folttmann
APV member

Objectives

This event is designed to highlight current hot topics in the field of pharmaceutical excipients:

- Data integrity in excipient manufacture and supply chain
- The new IPEC Quality Agreement Guide
- Appropriate stability testing using the IPEC Stability Program Guide
- Challenges of multi-compendial compliance for excipients
- Quality requirements for excipient packaging systems
- Challenges in a complex excipient supply chain – recent considerations
- Verification of excipient supplier compliance
- A commercial view: Overview of the global excipient market
- Formulation topics
  - o Diluents for direct compression
  - o Continuous manufacturing – excipient requirements
  - o Capsules – filling, interaction of formulation/excipients and release profiles of different capsule polymers
  - o Transdermal drug delivery: An industrial viewpoint
  - o Role of excipients in inhalation drug products
  - o ICH Q3D implementation by the European Pharmacopoeia

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

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

Hubertus Folttmann
Member of APV
BASF SE, Germany

Amina Faham
IPEC Europe Board member
Dow Chemical, Switzerland

Mahmud Yunis
IPEC Europe Board member
Biogrund GmbH, Germany

Programme

Tuesday, 19 September 2017 **08:30 to 18:00 h**

Registration

Opening/Welcome
Hubertus Folttmann, Specialist Strategic Marketing, Pharma Solutions, BASF SE, Germany
Frank Milek, Head of GMP and SHEQ Operations, Aug. Hedinger GmbH & Co. KG, Germany

Workshops 1-3
(The Workshops will run in parallel)

Workshop 1
Data Integrity –
How to apply in excipient manufacture and supply chain
- Re-labelling
- Transfer of Data
- Appropriate use
- Usability
- Disclosure of supply chain
- Master Data
- Traceability

Christa Färber, Staatl. Gewerbeaufsichtsamt Hannover, Germany
Eberhard Kwiatkowski, PHARMADVANTAGEIT Velbert, Germany

Workshop 2
Quality Agreements –
A simple Story!?
- What's new in IPEC Quality Agreement Guide & Templates?
- Applicability and correct use of the 3 templates – practical exercise
- Share & Learn: discuss recent examples, giving you* a headache

* please provide your topic 6 weeks prior to the workshop
Astrid Stockrahm-Uhling, DFE Pharma, Germany

Workshop 3
Stability testing of Excipients –
The IPEC Excipient Stability Program Guide (2010)
- Requirements of „The IPEC Excipient Stability Program Guide (2010)"
- Challenges for stability testing of excipients
- Practical approach – Design of an excipient stability testing program
- Discussion

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

Coffee Break and Table Top Exhibition

Repetition of Workshops 1-3
(The Workshops will run in parallel)

Review of workshops

Lunch Break and Table Top Exhibition

Challenges to ensure excipient compliance from development to market

Challenges of multi-compendial compliance for excipients
- Pharmacopoeial requirements in a global development context
- Status of pharmacopoeial harmonization
- Challenges and issues of multi-compendial compliance for excipients
- Functional related characteristics of excipients
- Requirements beyond pharmacopoeial compliance

Thomas Storm, Novartis, Switzerland

Leachables from the storage container of excipents – a possible source of impurities
- Guidelines and best practice guidance's for extraction studies of drug products.
- The permitted daily intake (PDI) and analytical evaluation threshold (AET) concept.
- Evaluation of extraction data.
- How does this translate to extractables and leachables from packaging materials of excipients?
- Which products may be at risk?
- A case study: Results of a PE extraction study.

Steven A. Watt, A&M STABTEST Labor für Analytik und Stabilitätsprüfung GmbH, Germany

Coffee Break and Table Top Exhibition

The need of the quality audit for the supply chain security of excipients
- Expectations
- The Quality audit reference standards
- Types of audit, scope & plan
- Security topics
- Identification and labelling
- To verify the supply chain map in audit
- Auditor awarenessand checks
- Refused audit: why and how to solve?
- Conclusion

Jean-Claude Soulé, Eli Lilly, France

IPEC Federation presents:
Challenges in a complex excipient supply chain – What changed since Haiti?
- State of play
- Standards and regulations for excipient supply chain
- Risk management in excipients supply chain
- The 2017 IPEC Federation GDP Guide for Excipients

Frank Milek, Vice-Chair to IPEC Europe, and a member of the IPEC Europe GDP Committee

Social programme

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

Programme

Wednesday, 20 September 2017 08:30 to 16:30 h

Implementation of ICH Q3D in the European Pharmacopoeia
- Introduction to the European Pharmacopoeia
- Revision strategy for general texts and impact
- Revision strategy for individual monographs

Bruno Spieldenner, European Directorate of the Quality of Medicines & Healthcare (EDQM) - Council of Europe, France

Overview of the global excipients market: focus on Oral Solid Dosage Forms
- Brief overview of the current state of the pharmaceutical industry
- The global excipients market
- Focus on the OSDF segment
- Key trends driving excipients consumption and their expected impact on the excipients market

Nikola Matic, Kline & Company, Czech Republic

Coffee Break *sponsored by* **and Table Top Exhibition** BIOGRUND FILMCOATING EXCELLENCE

Sustained release solid oral dosage forms & alcohol induced dose dumping
- Alcohol-Induced Dose Dumping (ADD)
- Kollidon® SR
- Polymers
- Matrix tablet
- Sustained-release
- Dissolution
- Drug release
- Leaching
- Pore former

Philipp Hebestreit, BASF SE, Germany

Excipients for Direct compression

Direct compression is the simplest and most cost-efficient process for tablet manufacturing.
- Challenges in direct compression: Excipient's key performance attributes.
- Classical DC fillers-binders
- Innovative DC fillers-binders: design by co-processing and other technologies

Laura de Miguel, Omya International *AG, Switzerland*

Lunch Break and Table Top Exhibition

Impact of excipients on the development of transdermal drug delivery systems (TDDS)
- Overview of excipients commonly used in TDDS
- Adhesives for TDDS
- Special properties of excipients to enhance penetration and permeation of the active pharmaceutical ingredient
- Evaluation of the Guidelines on the formalized risk assessment for excipients for the development of TDDS – a formulation developer's opinion

Sebastian Braun, tesa Labtec GmbH, Germany

Advanced imaging in pharmaceuticalmaterials
- *Electrostatics*
- Polymers
- Tomography
- Drug release
- Infinite focus microscopy

Kofi Asare-Addo, University of Huddersfield, United Kingdom

Coffee Break *sponsored by* **and Table Top Exhibition** BIOGRUND FILMCOATING EXCELLENCE

The use of excipients in pulmonary drug delivery
- Excipients used in nebulization
- Excipients used in metered-dose inhalers
- Excipients used in dry powder inhalers
- Influence of different lactose carriers on the deposition of salbutamol sulphate and budesonide from dry powder formulations
- Effects of fine lactose particles in dry powder inhaler formulations

Mats Hertel, University of Kiel, Germany

Closing remarks

Programme is subject to change

Exhibition and Sponsoring

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

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

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

Antonia Herbert, **ah@apv-mainz.de.**

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
- Lanyards
- Insert in bags
- Social programme
- Coffee breaks

sponsor:

BIOGRUND FILMCOATING EXCELLENCE
Colorcon
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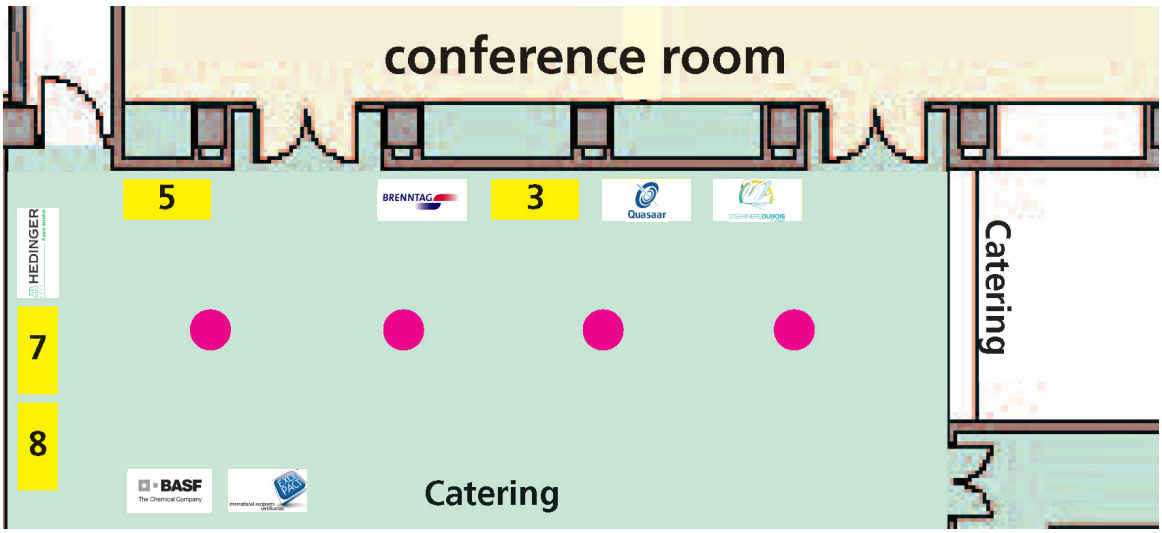


Floorplan

exhibitors:

BASF The Chemical Company
BRENNTAG
Quasaar
HEDINGER A pure decision.

Moderator / Speaker

Moderator and Speaker

Dr Hubertus Folttmann
BASF SE

Dr Hubertus Folttmann studied at the College of Pharmacy, Freie Universität Berlin and completed his doctorate studies in pharmaceutical chemistry at Heinrich Heine Universität Düsseldorf. After 12 years of experience in different functions at Knoll Group (2001 acquired by Abbott), he joined BASF in 1998. In his current function as Specialist Strategic Marketing, Pharma Solutions at BASF SE he is focusing on market intelligence and projects.

Dr Frank Milek
Aug. Hedinger GmbH & Co. KG

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).

Speaker

Dr Kofi Asare-Addo
University of Huddersfield

Kofi is a Senior Lecturer in Pharmaceutics and Pharmacy Admissions Tutor at the University of Huddersfield. Kofi obtained his PhD from the Medway School of Pharmacy, University of Kent, UK, supervised by Professor Ali Nokhodchi and Dr Ali Rajabi-Siahboomi. Kofi is also a Fellow of the Higher Education Academy and collaborates successfully with other Universities and several pharmaceutical industries. Kofi's research looks at improving the solubility of poorly soluble drugs using various particle engineering techniques in the view of improving bioavailability and other physicochemical and physicomechanical properties. His research also looks at using imaging to design robust formulations for oral drug delivery.

Dr Sebastian Braun
tesa Labtec GmbH

Dr Sebastian Braun studied at the university of Bielefeld focusing on antibiotic-resistance systems of microorganisms. After finishing his PhD in the field of analytical chemistry of endotoxins he joined the pharmaceutical industry and worked in the formulation and process development of Novosis AG (now Luye Pharma AG). Dr Braun joined tesa Labtec in 2009 with a strong focus on transdermal drug delivery systems and oral films. He is now manager of the formulation development department of tesa Labtec GmbH in Langenfeld.

Dr Laura de Miguel
Omya International AG

Dr Laura de Miguel is Manager Innovation and Technical Marketing for pharma/nutra applications at Omya International AG. She is a pharmacist graduated from University of Navarre and she holds a PhD in Pharmaceutical technology from Institut Galien Paris-Sud. Her current responsibilities involve managing the innovation portfolio and technical marketing activities in European and Middle-East countries.

Dr Christa Färber
Staatliches Gewerbeaufsichtsamt Hannover

Since 2005, after 12 years in the pharmaceutical industry, Dr Christa Färber has been working for the Staatliches Gewerbeaufsichtsamt Hannover where she is Head of the Inspectorate and responsible for GMP/GDP/GCP surveillance. She is a member of the German Expert Group EFG11 „Computerised Systems" and the APV Professional Group IT.

Dr Philipp Hebestreit
BASF SE

Philipp Hebestreit is a certified pharmacist and obtained a Doctor's degree at the Humboldt University, Berlin. He has been with BASF for 11 years.
After 5 years of global Regulatory Affairs responsibility and IPEC membership (with activities in IPEC Europe`s Regulatory Affairs Committee and IPEC Europe`s board), today Philipp is a regional Technical Marketing manager for Pharmaceutical Ingredients of BASF with both APV and IPEC activities.

Mats Hertel
University Kiel

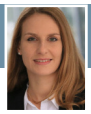
Mats Hertel studied pharmacy at Kiel University from October 2007 to November 2012 followed by his practical year. As part of that he accomplished a six months internship in the Department of Pharmaceutics and Biopharmaceutics of Kiel University under supervision of Prof Hartwig Steckel. In this time he worked on the development and characterization of pMDI and DPI formulations including device prototype testing. In March 2014 he started with his PhD under the supervision of Prof Steckel and PD Dr Scherließ at the University of Kiel.

Eberhard Kwiatkowski
PHARMADVANTAGEIT

Since 1995 Eberhard Kwiatkowski has been in charge of the computerised system validation first in the quality control then for the entire Bayer Pharma plant in the "GMP-Referat" for the API production in Wuppertal.
He is a co-author of the ISPE Good Practice Guide for the Audit of external suppliers and he is chair of SIG "raw data definition", a member of the GAMP-DACH Forum and he is also a member of APV's expert group on computerised systems. 2012 he founded his own consulting company.

Nikola Matic
Kline & Company

Based in Prague, Czech Republic, Nikola Matic is a Director of the Chemicals & Materials practice of Kline & Company. During his entire career, he has been closely monitoring and reporting on the specialty chemicals industry in various areas such as Personal Care Ingredients, Pharmaceutical Excipients, Emulsions Polymers, Biocides and Surfactants. Nikola currently holds global business responsibilities for the Chemicals & Materials department of Kline Market Research.
Prior to joining Kline, Nikola worked in the environmental services consultancy for a leading French company in which he was responsible for the business development in Central and Eastern Europe. Nikola holds an engineering degree in process engineering from the Université de Technologie de Compiègne (UTC).



Tanja Natterer
Aug. Hedinger GmbH & Co. KG

Tanja Natterer studied pharmacy at the University of Tübingen and is a specialist pharmacist for pharmaceutical analysis. She is working in the pharmaceutical qualitycontrol in the GMP Laboratory Hedinger, Stuttgart (Germany) since 2011. In her current function as head of quality control she is responsible for the stability testing program.

Dr Jean-Claude Soulé
Eli Lilly

After studies of bioengineering, industrial microbiology and a PhD in chemical engineering, Jean-Claude Soulé started his career at the International Research Center of Danone. Over his following 31 years within the parenteral pharmaceutical Industry he has worked for 3 different pharma companies (CRTS de Strasbourg, CENTEON and ELI LILLY) as Head of production of plasma derivates, oncolytics and human growth hormone manufacturing manager, recombinant enzymes production unit manager and validation manager. For the last 12 years he has the opportunities to design a complete supplier auditing process, mentor several auditors worldwide, and audit more than 400 times in many European countries, in USA, South and Central America, Maghreb, Africa, Middle East, China, Malaysia and Japan. He is currently Sr. Global Supplier Lead auditor and QA Consultant at Eli Lilly. He is experienced in auditing all the types of suppliers and service providers for the pharma industry including API, excipients, chemicals, medical devices, primary packaging, glass and rubber closures, printed materials, various critical consumables and laboratories. He faced periodically FDA, ANSM and various health authority inspectors.

Bruno Spieldenner
EDQM

Mr Bruno Spieldenner studied Physics and Chemistry at the University of Strasbourg and in 2006 he graduated a Master's degree in analytical chemistry and spectroscopy from the University of Marseille, in France.
After that he worked during 7 years as a laboratory engineer for a pharmaceutical company in Switzerland, where he was in charge of LC-MS/MS method development for both small and large molecules. There he got familiar with a broad set of analytical procedures used in quality control of medicinal products.
Since 2013, he joined the European Pharmacopoeia department of the EDQM in Strasbourg, where he is involved in the modernisation of texts on general methods and the implementation of the ICH Q3D Guideline.

Dipl-Ing Astrid Stockrahm-Uhling
DFE Pharma

Dipl-Ing Astrid Stockrahm-Uhling, Global QA Specialist, DFE Pharma. Astrid is a graduate in Chemical Engineering and initially worked for a Contract Research Organisation in execution of Phase I and II Clinical Trials. She then joined JANSSEN-CILAG in 1995, spending 6 years as Clinical Research Manager and another 5 years in Quality Assurance responsible for Clinical Drug Supplies. In 2007 she joined DFE Pharma and took up the position as QA Manager with overall responsibility for all QA and Regulatory activities worldwide. Since 2014 she is Internal Advisor for GMP compliance and the company's official representative in IPEC activities. Astrid is leading the task force responsible for the revision of the 2009 Quality Agreement Guide, and is also a member of the GMP Guide revision team.

Dr Thomas Storm
Novartis

Dr Thomas Storm studied Chemistry and Physics, and received a PhD in Environmental Technology from the Technical University Berlin. He started his career in Pharmaceutical Industry in 2001 at Schering AG in Berlin in Analytical Development. At Schering AG, and later at Bayer AG, he worked in early and late phase development projects, and was responsible for quality control of excipients for development. In 2008 he joined Inhalation Technical Development at Novartis Pharma AG in Basel, where he currently is heading a pharmaceutical development unit for inhaled dosage forms, that is responsible for formulation/process, analytical, and device development for early and late stage programs.

Dr Steven Watt
A&M STABTEST

After studying biology at the Bielefeld University and graduating with a PhD in genetics and molecular biology in 2005, Dr Steven Watt was granted a position as a postdoctoral candidate. There he was in charge of a mass spectrometry service unit, dealing with proteome and metabolome projects. In 2009 he joined Thermo Fisher Scientific as an instructor for scientific and pharmaceutical mass spectrometry applications. In his current position as a business development manager at A&M STABTEST he is involved in customer relations, marketing and the development of new analytical services in the field of pharmaceutical analysis.

Registration by fax +49 6131 9769-69

Location

Hotel Riu Plaza Berlin
Martin-Luther-Straße 1
10777 Berlin, Germany
www.riuplaza.com

Date

Course No. 3177
from 19 Sept. 2017 08:30 h
to 20 Sept. 2017 16:30 h

Registration fee

Early Bird Fee
before 30 June 2017
Industry 1490 EUR
Authorities 745 EUR
Plus VAT

Regular Fee
after 30 June 2017
Industry 1590 EUR
Authorities 795 EUR
Plus VAT

Coffee breaks, lunch, dinner and proceedings included.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de

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

Members of authorities pay half of the registration fee respectively.

Hotel reservation

Hotel Riu Plaza Berlin
Martin-Luther-Straße 1
10777 Berlin, Germany
www.riuplaza.com
E-mail:
reservations.berlin@riu.com
Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 11.08.2017
booking code: APV-IPEC
Special rate:
Single room incl. breakfast buffet from 129,- EUR per night.

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.

- ☐ pay via invoice
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*Mandatory

Please select **2** of the following workshop sessions (please tick only 2)

- ☐ Data Integrity
- ☐ Quality Agreements
- ☐ Stability testing of Excipients

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

- ☐ Yes
- ☐ No