APV/IPEC Europe Excipient Conference 2016

– An update on regulatory and application developments

20 to 21 September 2016
Prague, Czech Republic
Course No. 3163

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.

including 3 parallel workshop sessions

- ICH Q3D practical implementation challenges - a dual perspective - Manufacturer and excipient supplier
- Risk Assessment for Excipient GMP - Strategy to implement in a pharma company
- Atypical Actives - is there still a problem?

APV/IPEC Europe Excipient Conference 2016

– An update on regulatory and application developments

Dear Colleagues,

IPEC Europe and APV are delighted to invite you to our 5th annual conference on pharmaceutical excipients.
As in previous years the conference will focus on "hot topics" in the area of excipient regulation and technology.
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 the implementation of ICH Q3D, risk assessment for excipient GMP and atypical actives.
This year's regulatory session will highlight challenges of different international regulation in a global market with particular insights in regulatory requirements in Europe, in the United States and in China.
How non-harmonised excipient regulations are managed will be explained from a global pharma company's and an excipient supplier's point of view.
The technical and scientific part of the conference will be opened with a topic on drug-excipient interaction followed by the new regulatory situation of co-processed excipients and a way to fight counterfeiting. The drug formulation part of the programme includes excipients for biopharmaceuticals, nano-crystalline suspensions and how to overcome poor solubility of active ingredients. Last but not least you will get a comprehensive view on phospholipids and their pharmaceutical use.
With this program we tried to gather different aspects of excipients and combine regulatory and technical topics as they are the two sides of one coin.
Once again, 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 as well.
We are looking forward to welcoming you in Prague.

Frank Milek
Chair to IPEC Europe

Hubertus Folttmann
APV member

Objectives

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

- ICH Q3D implementation
- Risk assessment for excipient GMP
- Atypical Actives
- Differing international regulation in a global market
- Regulatory requirements for excipients
  - o in Europe
  - o in the USA
  - o in China
- Non-harmonised excipients from a pharma company's point of view
- Non-harmonised excipients from an excipient manufacturer's point of view

- Formulation topics
  - o Drug-excipient interaction
  - o Co-processed excipients
  - o Method to fight counterfeiting
  - o Excipients for biopharmaceuticals
  - o Nano-crystalline suspensions
  - o Formulation of poorly soluble actives
  - o Phospholipids – characteristics and use

ipec EUROPE
INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL

Programme

Tuesday, 20 September 2016 08:30 to 18:15 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

Three parallel workshop sessions:

Workshop 1
ICH Q3D practical implementation challenges - a dual perspective - API manufacturer and excipient supplier
- What is ICH Q3D? / What has changed?
- Examination of Practical Implementation Challenges and their impact on:
  - o API
  - o Manufacturing equipment
  - o Utilities
  - o Container closure system
  - o Excipients
- Development of a cross industry elemental impurity database

Cornel Venzago, Evonik, Germany

Workshop 2
Risk Assessment for Excipient GMP - Strategy to implement in a pharma company
- Overview of Regulations
- Industry perspective – Benefits/Challenges
- Practical Exercise

Frederik de Vos, Janssen, Belgium

Workshop 3
Atypical Actives - is there still a problem?
- What are these materials?
- What are the regulatory expectations?
- How are users and suppliers dealing with the regulatory expectations?
- What should IPEC be doing to address the remaining issues?

Iain Moore, Croda Europe Ltd., United Kingdom

Repetition of workshop sessions 1-3

Review of workshops

Challenges of different international regulation in a global market
How to manage non-harmonized requirements

Regulatory requirements for excipients in Europe
- EU regulatory requirements concerning manufacturers and users of excipients
- Recent changes to EU GMP Guidelines and their impact
- An Inspector calls - What does an MHRA Inspector expect to see during an inspection

Richard Andrews, MHRA, United Kingdom

How Excipients are regulated in the United States – Supplier and User Responsibilities
- Applicable excipient regulations in the US will be summarized.
- What are the Excipient Supplier's responsibilities to provide high quality excipients for drug applications?
- What must Excipient Users do when using Excipients in their drug products?
- How do the U.S. Excipient Regulations compare to the requirements in Europe and China?

Dave Schoneker, Colorcon, USA; IPEC Americas, USA

Coffee Break *sponsored by* **and Table Top Exhibition**

Regulatory requirements in China for excipients used in drug (domestic and imported)
- How Excipient is supervised to be used in domestic and imported drugs in China?
- What is the approval process for Excipient used in drugs, domestic Excipient and Imported Excipient?
- What specification is required for Excipient used in drugs in China?
- What is Excipient regulation trend in China?

Colin Li, Colorcon, China; IPEC China, China

How does a global pharma company manage non-harmonised excipient regulations?
- Pharmacopoeial challenges
- ICH challenges
- Regulatory challenges
- Case study
- Conclusions

David Elder, GSK Ware, United Kingdom

How to manage global acceptance of excipients in a non-harmonized regulatory environment?
- What are the critical regulations to observe in the respective regions (China, EU, Japan, US)?
- How to deal with diverging regulatory approaches?
- How to balance document efficacy and regulatory expectations for a globally marketed excipient?
- Which resources are critical?

Johanna Eisele, Evonik Nutrition & Care GmbH, Germany

Lunch Break and Table Top Exhibition

Social programme
Enjoy the walking tour at Prague castle through the 2nd courtyard, passing the office of the President (from outside) and St. Vitus Cathedral, the main church of Czech Republic.
Buffet style dinner will be served in a historical building of a monastery, where you have an amazing view.

Programme

Wednesday, 21 September 2015 8:30 to 16:30 h

Formyl impurities in PEG and degradation of a low dose compound: a tale of cooperation, collaboration, and scientific rigor leading to product robustness-by-design

- Discovery of formyl impurities in PEG on storage and in Drug Product
- Role of other excipients on the rate of formation of formyl impurities
- Stability implications on a low dose API
- Pharma-Vendor collaboration in understanding the cause and mitigating measures
- Product robustness through cross-organizational control strategy

Ajit S. Narang, Bristol-Myers Squibb, Co., USA

Co-processed Excipients and Regulations from an Industry Perspective

- Co-processed Excipients: Evolution
- Mission & Benefits; Regulatory Situation
- Initiatives; Considerations from an Industry Perspective

Franz-Karl Penz, Meggle, Germany

Coffee Break and Table Top Exhibition

Guardians protect from counterfeited drugs – novel primary packaging functionalities and encoding drug products.

- Monodisperse fractions of short PEG polymers are used for coding of solid dosage forms by blending these into coating followed by HPLC-CAD analysis.
- Other approaches are presented integrating metal-organic frameworks (MOF) into novel primary packaging images allows 24/7 surveillance of medication.

Lorenz Meinel, University of Würzburg, Germany

Excipients for biopharmaceuticals – functions and needs

- Effects of buffer, salt, sugars in protein formulation
- Stabilization of protein formulations by surfactants
- Challenges with surfactants in protein formulation
- Potential for new excipients

Wolfgang Frieß, Ludwig-Maximilians-Universitaet Munich, Germany

Lunch Break and Table Top Exhibition

Selection of wetting / dispersing agent for the preparation of nano-crystalline suspensions by top down process

- The general strategy ('fast-to-patient') in pharmaceutical industry is to test a new API in a target patient population as quickly as possible.
- The screening methodology, based only on physico-chemistry, would provide a lot of scientific information but would be very time and resources consuming
- In contrary, a purely empirical methodology (e.g. design of experiment, trial error approach) may provide a quick solution with poor scientific information.
- Use a compromise between purely scientific and purely empirical methodology in order to achieve both time effectiveness and scientific information.

Mostafa Nakach, Sanofi, France

Successful Formulation of Poorly Soluble Actives – Suitable Combination of Technologies and Excipients

- What is the solubility challenge? How does the chemical drug space look like?
- Typical formulation approaches for poorly soluble actives such as amorphous solid dispersions and self-emulsifying drug delivery systems
- Two main fields to work on to solubilize a drug: (i) achieving high kinetic solubility (super-saturation) and reducing precipation from super-saturation
- Typical excipients for and their role for the different formulation approaches

Andreas Gryczke, BASF SE, Germany

Coffee Break *sponsored by* **and Table Top Exhibition**

A Practical View on the Use of Phospholipids in Pharmaceutical Formulations

- Lecithins and phospholipids are widely used in pharmaceutical formulations. The differences between natural (derived from plants or egg) lecithins and phospholipids, hydrogenated and synthetic phospholipids are summarized with regard to the production, the regulatory requirements, the analyses, the physico-chemical properties and the use
- The pharmaceutical industrial characteristics of natural and synthetic phospholipid excipients are compared.

Peter van Hoogevest, Lipoid GmbH, Germany

Closing remarks

Programme is subject to change

Exhibition and Sponsoring

Tabletop 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

exhibitors:

table 1: Croda

table 2: BASF

table 3: SEPPIC

table 4: Hedinger

table 5: Omya

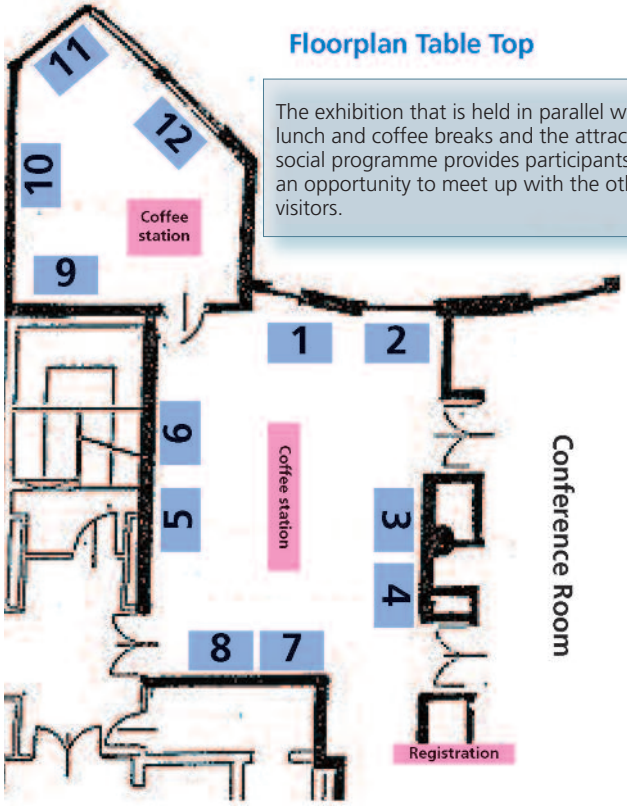
table 6: Brenntag

table 7: DFE Pharma

APV/IPEC Europe Excipient Conference 2016

Floorplan Table Top

The exhibition that is held in parallel with lunch and coffee breaks and the attractive social programme provides participants with an opportunity to meet up with the other visitors.



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 – **sold**
- Lanyards – **sold**
- Insert in bags
- Social programme
- Coffee breaks – **sold**
- etc.

For detailed information about exhibition and the different sponsoring options, please go to our website www.apv-mainz.de or contact Antonia Herbert, ah@apv-mainz.de.

sponsors:

Moderator / Speaker

Moderator

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 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 chair of the International Pharmaceutical Excipients Council Europe (IPEC Europe)

Speaker

Richard Andrews
Unit Manager Inspectorate Operations
Medicines and Healthcare products Regulatory Agency (MHRA)
Richard joined the MHRA as a GMP Inspector in 2001 and is currently a Unit Manager with responsibility for the GMP and GPvP Inspection teams. Prior to joining the MHRA Richard worked in the pharmaceutical industry for 17 years focusing mainly on the manufacture of bulk active pharmaceutical ingredients. He has experience of process development and technical support and has held managerial positions in both QA and production. Whilst at the MHRA, in addition to the inspection of a wide range of pharmaceutical manufacturers, Richard has been an Operations Manager with responsibility for teams of both GMP and GDP Inspectors and was part of the Agency team responsible for implementing the changes arising from the EU Falsified Medicines Directive.

Frederik de Vos is an Industrial Pharmacist (QP). He have been working with Janssen for 10 years now and after roles in Drug Product QA and QC he has spent the last 5 years in Supplier Quality, focusing now on Biologics. He is still the team's SME on Excipients and represent the Pharma segment within the enterprise J&J team working on chemicals. He have been part of IPEC Europe since 2010 and is active in the Quality/Regulatory Affairs and GDP Committees. He is also part of the IPEC Europe Taskforce that has written the How to Do document related to the implementation of the Risk Assessment Guideline.

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

Over his 39 years within the Industry **David Philip Elder, PhD**, has worked for 3 different companies (GSK, Syntex and Sterling Winthrop) and he had roles of increasing seniority covering diverse roles in product development. He has extensive experience of the regulatory process (MAAs, IMPDs, NDAs, INDs, JNDAs) and he had taken three different products to the market (Seroxat oral suspension; Seroxat controlled release tablets and Avamys intranasal suspension).

Prof. Dr. Wolfgang Frieß holds a position as Professor for Pharmaceutical Technology and Biopharmaceutics at the LMU Munich since 2001. He received his PhD in Pharmaceutical Technology in 1993 and his Pharmacy degree in 1989 from the University of Erlangen. His primary research goals are protein formulation, drug delivery and biomaterials, in particular new analytical tools for protein formulations, freeze-drying of proteins and different local delivery routes. He has worked for several years in academia both in Germany and the US. He is co-editor of the European Journal of Pharmaceutics and Biopharmaceutics and has published over 130 research papers, patents and book chapters.

In his current position in Global Development and Technical Marketing Pharma Ingredients and Services at BASF SE, Germany, **Andreas Gryczke** is a team leader in Global Development and Technical Marketing and is responsible for the technical solubilisation platform. The platform deals with different kind of drug delivery technologies such as self-emulsifying drug delivery systems, amorphous solid dispersions, drug-excipient interactions, etc. Andreas' expertise is mainly on Solubility

Colin Li is the Chair-Elect of IPEC China (will be Chair of IPEC China in July, 2016), IPEC China Primary Representative of IPEC Federation and Regulatory Affairs Manager of Colorcon (China). He is a Licensed Pharmacist and has made speach on Excipient related topics at many different conferences.
He graduated from ShenYang Pharmaceutical University majoring in Pharmaceutics with almost 20 years working experiences at quality and regulatory affairs department in the pharmaceutical industry including multinational companies like Allegan, Sanofi and Colorcon etc.

Prof. Dr. Dr. Lorenz Meinel studied pharmacy at the University of Würzburg, received his Dr. sc. nat. (ETH Zürich; awarded with the Silver medal of ETH Zürich for outstanding doctoral theses) in 2002, his Dr. rer. med. (Universität Frankfurt, summa cum laude) in 2005, and his Habilitation and venia legendi for Pharmaceutics from ETH Zürich in 2007. In between he was Postdoc for 2 years at the Massachusetts Institute of Technology (MIT), USA. From 2005 to 2007 he was director in Technical R&D and from 2007 to 2010 director in Translational Medicine at Novartis Pharmaceuticals AG (Basel). Since 2010 he is director of the Chair for drug formulation, delivery, and biopharmacy at the University of Würzburg.

Speaker

Dr. Iain Moore is Global Head of Quality Assurance Croda Europe Ltd, a manufacturer of speciality and performance chemicals based in the United Kingdom. After completing his doctorate studies in organometallic chemistry he joined BP Chemicals to research and develop C1chemistry. Since moving to Croda in 1987, he has acted at the technical – customer interface, led a team of chemists in the development of Croda's products before holding various QA roles since 1995. This includes implementing Excipient and API GMP systems at two manufacturing sites, including two successful MHRA inspections. He is one of the co-authors of the PQG PS 9100:2002 guide for pharmaceutical excipients, the IPEC-PQG GMP Guide for Pharmaceutical Excipients and the EFfCI GMP Guide and standard 2012 for Cosmetic Ingredients. He is past chair of the IPEC Europe GMP Committee and is currently President of the Board of EXCIPACT asbl.

Mostafa Nakach is a Pharmaceutical engineer from Ecole des Mines d'Albi and a Master 2 graduate from Paris-sud 11 university in Pharmaceutical technology and biopharmacy. He is preparing thesis on stabilization and production of nanocrystalline suspensions. He is working within sanofi group since 28 years. His current position is a head of pharmaceutical engineering section within pharmaceutical science operations.
Mostafa Nakach worked also as API physical quality research engineer within chemical development department. His mission was focused on the process development of solid chain: from crystallization to particles engineering.

Ajit S. Narang, Ph.D. is a results-driven people-focused manager and technical contributor and with over 13 years of broad and direct experience in end-to-end Drug Product development.
He held positions with increasing responsibility in the design, development, and technology transfer of several early and late stage clinical and commercial oral solid drug products. He has operational regulatory competence and experience in several regulatory interactions, face-to-face FDA type II meeting interactions, preparation of regulatory documents, responding to regulatory questions, and interactions with internal regulatory departments and in diverse regulatory pathways [(IND/NDA/ANDA/505(B2))].
He has technical expertise and scientific depth. Credited with more than 40 manuscripts/book chapters, 7 patents, numerous external presentations, and invited lectures.

Dr. Franz K. Penz is Head of Technical Department at Meggle BG E & T, a lactose-based excipient manufacturer in drug, food, nutritional and related industries. He earned his license to practice pharmacy and a PhD from LMU University in Munich (Germany). Prior to joining Meggle he had various experiences in biochemical and medical research focused projects. He started his professional career in hospital pharmacy.
His present areas of interest and publication are found in the fields of solid dosage form pharmaceutics and pharmaceutical technology emphasizing co-processed excipients. He accompanied several immediate and modified-release excipients from creative idea implementation to commercial launch and is responsible for its ongoing characterization and new applications. Dr. Penz works primarily in Europe and French speaking countries all over the world, current responsibilities include technical marketing, aspects of regulatory affairs, formulation support, and training, as well as innovation strategies.

David R. Schoneker is the Director of Global Regulatory Affairs at Colorcon. His responsibilities include global coordination of Colorcon's worldwide regulatory activities and market expansion projects to gain regulatory acceptance of Colorcon's products and components for various target markets. His previous position at Colorcon was Director of Quality Assurance and Quality Control.
Mr. Schoneker was the Chairman of IPEC-Americas during the period 2007-2009 and is currently a member of the Executive Committee. He is now serving as the Vice Chair of Scientific and Regulatory Affairs 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, 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 groups and Partnerships around the world.

After having several positions at Ciba Ltd. and Novartis Ltd. **Dr. Peter van Hoogevest** founded in 1998 together with colleagues the company ADD Advanced Drug Delivery Technologies and became CEO of this company and was member of the Board of Directors. In 2000 he joined Phares Drug Delivery AG, a company specialized in the delivery of poorly water soluble drug substances, as Managing Director and COO and member of the Board of Directors. Since 2012 he is Managing Director of the Phospholipid Research Center, Heidelberg and Head of the Scientific Department (including the Development Department) of Lipoid GmbH, Ludwigshafen am Rhein, Germany.

Cornel Venzago is Head of Inorganic Analytics at Evonik Industries, Productline Analytics (former AQura and Degussa). His labs cover techniques like GD-MS, ICP-MS, ICP-OES, AAS, XRF, and XRD, performing analytical research and development as well as quality control for materials science, chemical and pharmaceutical industries. Cornel Venzago has over 20 years experience of trace metals analyses of pharmaceutical products. Since some years he is a member of the IPEC Coalition for the Rational Implementation of the Elemental Impurities Requirements and is also a member of the IPEC Europe elemental impurities task force. He has published some papers on the method development for elemental impurities in pharmaceuticals and has held several workshops and lectures on this subject.

Registration by fax +49 6131 9769-69

Location

Hotel Don Giovanni Prague
Vinohradská 157a
13020 Prague
Tel.: +420 26703-1111
Fax: +420 26703-6717
http://www.hotelgiovanni.cz

Date

Course No. 3163
from 20 Sept. 2016 08:30 h
to 21 Sept. 2016 16:30 h

Registration fee

Early Bird Fee
until 30 June 2016
APV/IPEC member 1360 EUR
Non-member 1490 EUR
Plus VAT

Regular Fee
after 30 June 2016
APV/IPEC member 1460 EUR
Non-member 1590 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 APV member's and non-member's registration fee respectively.

Hotel reservation

Hotel Don Giovanni Prague
Vinohradská 157a
13020 Prague
Tel.: +420 26703-1111
Fax: +420 26703-6717
E-mail: reservations@hotel-giovanni.cz

Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 28 June 2016.
booking code: APV-IPEC
Special rate:
Single room incl. breakfast buffet from EUR 105,00 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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  - ☐ Visa
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*Mandatory

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

- ☐ ICH Q3D practical implementation challenges - a dual perspective - Manufacturer and excipient supplier
- ☐ Risk Assessment for Excipient GMP - Strategy to implement in a pharma company
- ☐ Atypical Actives - is there still a problem?

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

- ☐ Yes
- ☐ No

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