

# APV/IPEC Europe Excipient Conference 2015

– An update on regulatory and application developments



23 to 24 September 2015  
Barcelona, Spain

Course No. 3144

## 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
- Change Management of Excipients according to IPEC Significant Change Guide
  - Risk Assessment for Excipient GMP
  - How to Establish a Quality Agreement for Excipients

# APV/IPEC Europe Excipient Conference 2015

## – An update on regulatory and application developments

Dear Colleagues,

IPEC Europe and APV are delighted to invite you once again to our annual conference on pharmaceutical excipients. As in previous years the conference will focus on “hot topics” in the area of excipient regulation and technology. Along with a comprehensive and thought-provoking conference 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 change management, risk management and quality agreements, topics which will have a lot of impact on the pharmaceutical industry and suppliers alike.

This year’s regulatory session will highlight the new ICH Q3D guideline on elemental impurities and the changes to EU GMP Guidelines Part 1 (chapter 5) which will create a lot of work for industry in the future. Different views will be presented and discussed from a European perspective, and we will also look at developments on the other side of the Atlantic and discuss the impact of new US regulation on the supply of excipients.

The technical and scientific part of the conference will be opened with a compendial topic presented by EDQM. All other presentations in this session will focus on the role of excipients and their function in dosage forms. 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 hope you will agree that the topics covered include some really pressing issues affecting excipients, and we are looking forward to welcoming you in Barcelona.



Hubertus Foltmann  
Board Member of IPEC Europe



Frank Milek  
Chair to IPEC Europe

## Objectives

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

- Change management of excipients
- Risk assessment for excipient GMP
- Quality agreements for excipients
- ICH Q3D - Elemental Impurities
- New supplier qualification requirements in the EU
- Impact of FDASIA and GDUFA on excipient use in the US
- New developments/trends in
  - o Capsule shell materials
  - o Orodispersible dosage forms
  - o Transdermal patches
  - o Recombinant human serum albumin as excipient
  - o Functional characterization of excipients
  - o High purity excipient considerations
  - o And more



# Programme

Wednesday, 23 September 2015 09:00 to 17:30 h

## Registration

### Opening/Welcome

*Hubertus Foltmann, BASF SE, Germany;*

Board Member of IPEC Europe

*Frank Milek, Aug. Hedinger GmbH & Co. KG, Germany;*

Chair to IPEC Europe

### Three parallel workshop sessions:

#### Workshop 1:

#### Change Management of Excipients according to IPEC Significant Change Guide

– How to implement an MOC system

- Overview of the latest revision of the IPEC Significant Change Guide
- Case studies of how to use the guide for interpretation of the significance of change
- Practical workshop exercise and discussion

*Kevin McGlue, Colorcon Ltd., United Kingdom*

#### Workshop 2:

#### Risk Assessment for Excipient GMP

– How to apply the new EU Guide

- Introduction – excipients and excipient diversity
- The Guidelines
- Q&A session on those
- EXCiPACT Introduction and use
- Worked examples using the guideline to determine the GMP needed

*Iain Moore, Croda International plc., United Kingdom*

#### Workshop 3:

#### How to Establish a Quality Agreement for Excipients

– Joint effort for supplier and customer

- Requirements for quality agreements in regulation
- IPEC recommendations for a standard quality agreement
- How to establish a quality agreement acceptable for supplier and user
- Interpretation of phrases commonly used

*Frank Milek, Aug. Hedinger GmbH & Co. KG, Germany;*

Chair to IPEC Europe

## Lunch Break and Table Top Exhibition

### ICH Q3D - Elemental Impurities

– Content and implementation strategies

- Q3D guideline and its implementation
- Feedback in EU regulation and Ph Eur, rest of the world
- Role of IPEC federation

*Henk de Jong, International Pharmaceutical Federation, France*

### Global regulatory compliance strategy for excipients

- Map key regulatory changes and issues
- Compliance monitoring and prioritization based on risk
- Address compliance implementation challenges

*Patricia Rafidison, Dow Corning, France*

### New supplier qualification requirements in the EU

– Impact and implementation of the new chapter 5 EU GMP Part 1:

### Changes in chapter 5 relating to supplier qualification

– An introduction

*Frank Milek, Aug. Hedinger GmbH & Co. KG, Germany;*

Chair to IPEC Europe

### Supplier audits

– How to cope with more audits

- The application of a risk based approach to the selection and classification of excipient suppliers
- Supplier performance monitoring
- Audit frequency and audit duration
- Conduction of and follow-up to supplier audits
- Supply chain traceability

*Raymond Lyons, Merck Sharp & Dohme, Netherlands*

## Coffee Break and Table Top Exhibition

### How to evaluate and secure the whole excipient supply chain

- Regulatory Background
- Supply Chain Qualification
- Risk Based Approach
- Monitoring and Control Processes

*Jesus Rivas, Novartis, Switzerland*

### Reduced incoming testing

– What will change and how this can be managed?

- Reduced testing and in- and outsourcing of testing according to marketing authorisation dossier, strategy
- How to handle outsourcing testing and qualification of such testing
- Strategies for testing

*Gert Boge Winther, Novo Nordisk, Denmark*

## Social programme



*Let yourself be surprised by a balanced programme of dinner and a guided tour of Barcelona, Catalonia's capital and city of art, music and Gaudi.*

# Programme

**Thursday, 24 September 2015 8:30 to 16:30 h**

## **Impact of FDASIA and GDUFA on Excipient Use in the US** – Supply Chain and Formulation Implication

- The excipients are getting more attention in terms of their role in ensuring patient safety
- This presentation will cover the aspects of FDASIA and GDUFA that have the most impact on excipients in regard to the supply chain and their use by formulators
- Current industry thinking on the potential impact of these with respect to excipients will also be reviewed

*Priscilla Zawislak, Ashland Inc., United States;*  
*IPEC-Americas, United States*

## **Excipients in the European Pharmacopoeia**

– Current hot topics

- Excipients in the European Pharmacopoeia
- Excipients in the international harmonisation
- Excipients and Q3D

*Ulrich Rose, EDQM, France*

## **Coffee Break and Table Top Exhibition**

### **Beyond gelatin – New polymers for pharmaceutical capsules**

– Characteristics, properties and specifications

- Review the advanced in two piece capsule development over the past decade and its applications
- Capsule characteristics, properties, specifications and in vitro – in vivo performance
- Applications and case studies

*Sven Stegemann, Graz University of Technology, Austria;*  
*Capsugel, Belgium*

### **Considerations in the development of Orodispersible tablets (ODTs)**

- Why ODTs: Compliance, pediatric and geriatric considerations, life style & convenience
- Regulatory framework: Pediatric, quality and safety considerations, examples of suitable excipients available in the market
- Role of functional excipients for ODTs: Performance and functionality
- Options: Ready to use vs. in-house formulations

*Philipp Hebestreit, BASF SE, Germany*

## **Lunch Break and Table Top Exhibition**

### **Recombinant human serum albumin as an excipient**

- How human serum albumin function as a stabilizer in formulations and the recovery process
- Comparison of plasma versus recombinant human serum albumin
- Practicalities when using human serum albumin in

formulation – API analysis in the presence of albumin, viscosity from albumin etc.

*Mikael Bjerg Caspersen, Novozymes Biopharma, United Kingdom*

### **Self-emulsifying lipid formulations**

SELFs are the preferred enabling technology to increase the bioavailability of poorly soluble drugs, especially in the case of lipophilic compounds.

- Overview of the main advantages to formulate lipid-based systems
- Review of
  - the different types of lipid formulations
  - the main types of excipients
  - the typical manufacturing processes
  - the specific characterization techniques.

*Vincent Jannin, Gattefossé SAS, France*

### **Functional characterization of excipients**

– Beyond Compendia

- Overview of the difference between compendial tests and standards and functional tests of excipients
- Consideration of alternative testing procedures/data collection to identify critical quality attributes of the excipient not controlled by the compendial specification
- Potential excipient attributes that may have an impact on drug product quality
- Alignment of functional characterization of excipients with Quality by Design principles

*Hannes Leisch, Novartis Pharma AG, Switzerland*

### **High Purity Excipient Considerations in Pharma and Biopharma**

- A focus on excipient quality offers the opportunity to not only enhance the profile of a drug, but additionally supports a streamlined and accelerated effort throughout all development phases
- Discuss the critical impact of excipient choice in meeting some of the key challenges faced by pharmaceutical formulators, primarily in the areas of drug solubilisation, stability and delivery

*Steve Mellor, Croda Europe Ltd., United Kingdom*

### **Closing remarks**

Programme is subject to change





# Exhibition and Sponsoring

## Tabletop Exhibition

As well as in the last three 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



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 with documentation
- Meeting bags
- Lanyards
- Insert in bags
- Social programme
- Coffee breaks
- etc.

For detailed information about exhibition and the different sponsoring options, please go to our website [www.apv-mainz.de](http://www.apv-mainz.de) or contact Antonia Herbert, [ah@apv-mainz.de](mailto:ah@apv-mainz.de).

## Chairs and Speaker



**Hubertus Foltmann**  
Product Management Pharmaceutical Excipients,  
BASF SE, Germany;  
Board Member of IPEC Europe



**Frank Milek**  
Head of GMP and SHEQ Operations,  
Aug. Hedinger GmbH & Co. KG, Germany;  
Chair to IPEC Europe



**Mikael Bjerg Caspersen**  
Senior Professional,  
Novozymes Biopharma United Kingdom Ltd.



**Henk de Jong**  
Scientific Secretary,  
International Pharmaceutical Federation, France



**Philipp Hebestreit**  
Manager Technical Service Pharma Ingredients &  
Services Europe,  
BASF SE, Germany



**Raymond Lyons**  
Associate Director Quality Systems & Compliance  
and GMP auditor within the EMEA (Europe-  
Middle-East-Africa) Divisional Auditing Group of  
Merck Sharp & Dohme, Netherlands



**Kevin McGlue**  
Director Global Quality Assurance, Colorcon Ltd.,  
United Kingdom



**Vincent Jannin**  
Pharmaceutical Research Director GATTEFOSE  
SAS, France;  
Vice-President APGI – Int. Society for  
Drug Delivery Science and Technology, France



**Steve Mellor**  
Health Care Technology Development Director,  
Croda, Europe Ltd.



**Iain Moore**  
Head of Global Quality Assurance,  
Croda International plc., United Kingdom



**Patricia Rafidison**  
Global Regulatory affairs and compliance  
manager,  
Dow Corning, France



**Jesus Rivas**  
Global Lead for Sourcing QA,  
Novartis Pharma AG, Switzerland



**Ulrich Rose**  
Head of Division A of the EDQM's European  
Pharmacopoeia Department,  
European Directorate for the Quality of medicines  
and Health Care, Council of Europe, France



**Hannes Leisch**  
Senior QC Facilitator  
Novartis Pharma AG, Switzerland



**Sven Stegemann**  
Professor for Patient Centric Drug Development  
and Manufacturing,  
Graz University of Technology, Austria;  
Capsugel, Belgium



**Gert Boge Winther**  
Specialist Sourcing QA Raw Materials,  
Novo Nordisk, Denmark



**Priscilla Zawislak**  
Global Regulatory Affairs Manager,  
Ashland Inc, United States;  
IPEC-Americas, United States

## Location

Novotel Barcelona City  
Avinguda Diagonal 201,  
08018 Barcelona, Spain  
Tel. (+34) 9332 62499  
Fax. (+34) 9332 08779  
h5560@accor.com

## Date

Course No. 3144  
from 23 Sept. 2015 09:30 h  
to 24 Sept. 2015 16:30 h

## Registration fee

**Early Bird Fee**  
*until 30 June 2015*  
APV/IPEC member 1360 EUR  
Non-member 1490 EUR  
Plus VAT

**Regular Fee**  
*after 30 June 2015*  
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 registrati-  
on fee respectively.

## Hotel reservation

Novotel Barcelona City  
Avinguda Diagonal 201,  
08018 Barcelona, Spain  
Tel. (+34) 9332 62499  
Fax. (+34) 9332 08779  
h5560@accor.com

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

Deadline for special confe-  
rence rate: 28 August 2015.

Special rate:  
Single room incl. breakfast  
buffet from EUR 130,00 per  
night.

### Registration

As soon as you have found a seminar of your inter-  
est, 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 questi-  
ons 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 parti-  
cipation. 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 sugges-  
tions and critique that might arise during the  
seminar and will certainly help you with further  
questions you may have.

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

- Change Management of Excipients acc to IPEC Significant Change Guide  
 Risk Assessment for Excipient GMP  
 How to Establish a Quality Agreement for Excipients

**The registration also includes the participation in the Social Event.**

Please let us know if you wish to attend:

- Yes  
 No

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