APV/IPEC Europe Excipient Conference 2014

– An update on regulatory and application developments

23 to 24 September 2014

Düsseldorf, Germany

Course No. 3128

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.

MAKING SCIENCE WORK

APV/IPEC Europe Excipient Conference 2014

– An update on regulatory and application developments

Dear Colleagues,

The success of the excipient conferences jointly organised by APV and IPEC Europe in the last years motivated us to continue also 2014. This year we put together a program focusing on two major areas: regulation and application.
In the field of regulation we will give a broad view on excipient regulation in Europe, the USA and emerging countries and would like to discuss with the audience the impact on our business. Excipient suppliers are more and more in the focus of regulators and drug manufacturers. This is reflected in topics on supplier qualification, marketing authorization dossiers and excipient quality system standards. Application related topics of the conference will be on pediatrics, parenterals, biopharmaceuticals, Quality by Design and novel excipients.
With this selection of subjects we would like to cover the range of current hot topics and allow participants to discuss the topics with experts. There will be enough opportunities for networking and learning about different subjects to broaden our horizon in the area of pharmaceutical excipients.

On behalf of IPEC Europe and APV it will be a great pleasure for us to welcome you to the conference 2014.

Hubertus Folttmann
Board Member of APV and IPEC Europe

Frank Milek
Chair to IPEC Europe

Objectives

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

- Regulatory environment – key changes in Europe, USA and emerging countries
- Supplier qualification practice
- Excipients in marketing authorization dossiers
- Excipient quality system standards
- Excipients in pediatrics, parenterals and biopharmaceuticals
- Novel excipients
- Quality by Design

ipec EUROPE

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL

Programme

Tuesday, 23 September 2014 08:30 to 11:30 h

Pre-conference workshop
Iain Moore, Croda Europe Ltd., United Kingdom

Tuesday, 23 September 2014 12:30 to 18:00 h

Opening/Welcome
Hubertus Folttmann
Global Marketing Active Pharmaceutical Ingredients – Pharma Ingredients & Services, BASF SE, Germany
Frank Milek
Head of GMP and SHEQ Operations,
Aug. Hedinger GmbH & Co. KG, Germany

Regulatory environment - Key changes in the last ten years, trends and future

- **From the European perspective**

Richard Andrews, MHRA, United Kingdom

- **From the US perspective** (remote presentation)

Steven Wolfgang, US Food and Drug Administration, United States

- **From an emerging markets perspective (India, China, Brazil)**

Dave Schoneker, IPEC-Americas, United States

How to qualify excipient suppliers?
Harald Scheidecker, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Information on excipients required in a marketing authorisation dossier
Wolf-Ruediger Schlag, BASF SE, Germany

Excipient quality system standards
Helen Stubbs, Dow Chemical, Switzerland

EXCiPACT™
Iain Moore, Croda Europe Ltd., United Kingdom

Social programme

Wednesday, 24 September 2014 8:30 to 15:30 h

Excipients for pediatric use
Jörg Breitkreutz, University of Düsseldorf, Germany

Critical raw material components for use in biopharmaceutical API manufacturing – requirements and challenges
Mathieu Ballie, Novartis Pharma AG, Switzerland

Excipients for use in parenteral products - functions, requirements and trends
Thomas Froneck, Vetter Pharma-Fertigung GmbH & Co. KG, Germany

Quality-by-Design - understanding how excipient properties influence drug product performance
Amina Faham, Dow Chemical, Switzerland

Podium discussion
Regulatory challenges - paving your way to GMP compliance
How to cope with excipient compliance expectations?
Podium discussion led by
Amina Faham, Dow Chemical, Switzerland
Patricia Rafidison, Dow Corning, France

Creating value with novel excipients: a case study
Vincent Lenaerts, Apidel SA, Switzerland

Closing remarks

Programme is subject to change

Pre-conference workshop

The publication of the guidelines on the Formalised Risk Assessment for Ascertaining the Appropriate GMP for Excipients, the European Commission highlighted best practices for excipient supplier qualification.

This workshop will take you step by step through the guidelines and follow up with some case studies which will allow you to practice applying the principles and tools in this document.

Note: All registrants will receive a pre-workshop copy of the guideline with the registration confirmation – and are asked to read it prior to the session.

- 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

Exhibition and Sponsoring

Tabletop Exhibition

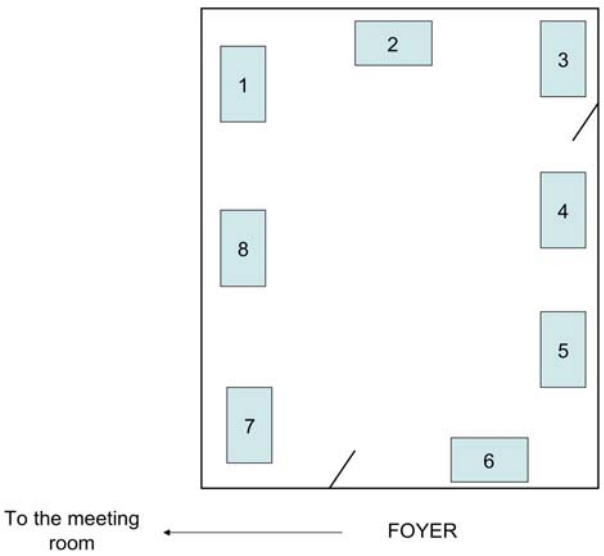
As well as in the last two years, we are offering you the opportunitiy to present your company, products and services to a truly focused target market. Here you can reach everyone dealing with excipients without wastage.

A tabletop includes:

- one table
- two chairs
- electricity

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.

More information can be found on www.apv-mainz.de or by contacting Katrin Kälkert, kk@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 with documentation
- Meeting bags
- Lanyards
- Insert in bags
- Social programme
- Coffee breaks
- etc.

For detailed information about the different sponsoring options, please go to our website www.apv-mainz.de or contact Katrin Kälkert, kk@apv-mainz.de.

Registration by fax +49 6131 9769-69

Location

Holiday Inn Düsseldorf
Airport-Ratingen
Broichhofstr. 3
40880 Ratingen, Germany
Telefon: +49 2102 456-0
Telefax: +49 2102 456-444

Date

Course No. 3128
Pre-Conference Workshop
from 23 Sept. 2014 08:30
to 23 Sept. 2014 11:30
Conference
from 23 Sept. 2014 12:30
to 24 Sept. 2014 15:30

Registration fee

APV/IPEC member	1360 EUR
+ Workshop	1660 EUR
Non-member	1490 EUR
+ Workshop	1790 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

Holiday Inn Düsseldorf
Airport-Ratingen
Broichhofstr. 3
40880 Ratingen, Germany
Telefon: +49 2102 456-0
Telefax: +49 2102 456-444

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

Deadline for special conference rate: 1 September 2014.

Special rate:
Single room incl. breakfast buffet from EUR 99,00 per night.

Mainz, March 2014

Registration

- ☐ with pre-conference workshop
- ☐ without pre-conference workshop

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
- ☐ pay via Credit Card (fill in below)
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Date* Signature*

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APV GmbH

www.apv-mainz.de

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