



Speakers

Sabine Atzor

*European Commission,
Belgium*

Katrin Nodop

EMA, United Kingdom

Bronwyn Phillips

MHRA, United Kingdom

Steven Wolfgang

FDA, USA

Edwin Rivera

FDA, USA

Johanna Eisele

*Evonik Röhm GmbH,
Germany*

Felicitas Guth

BASF, Germany

Kevin McGlue

Colorcon, United Kingdom

Frank Milek

Aug. Hedinger, Germany

Iain Moore

Croda, United Kingdom

Stephan Peeters

*Janssen Pharmaceutica,
Belgium*

Richard Smalley

UCB Pharma, Belgium

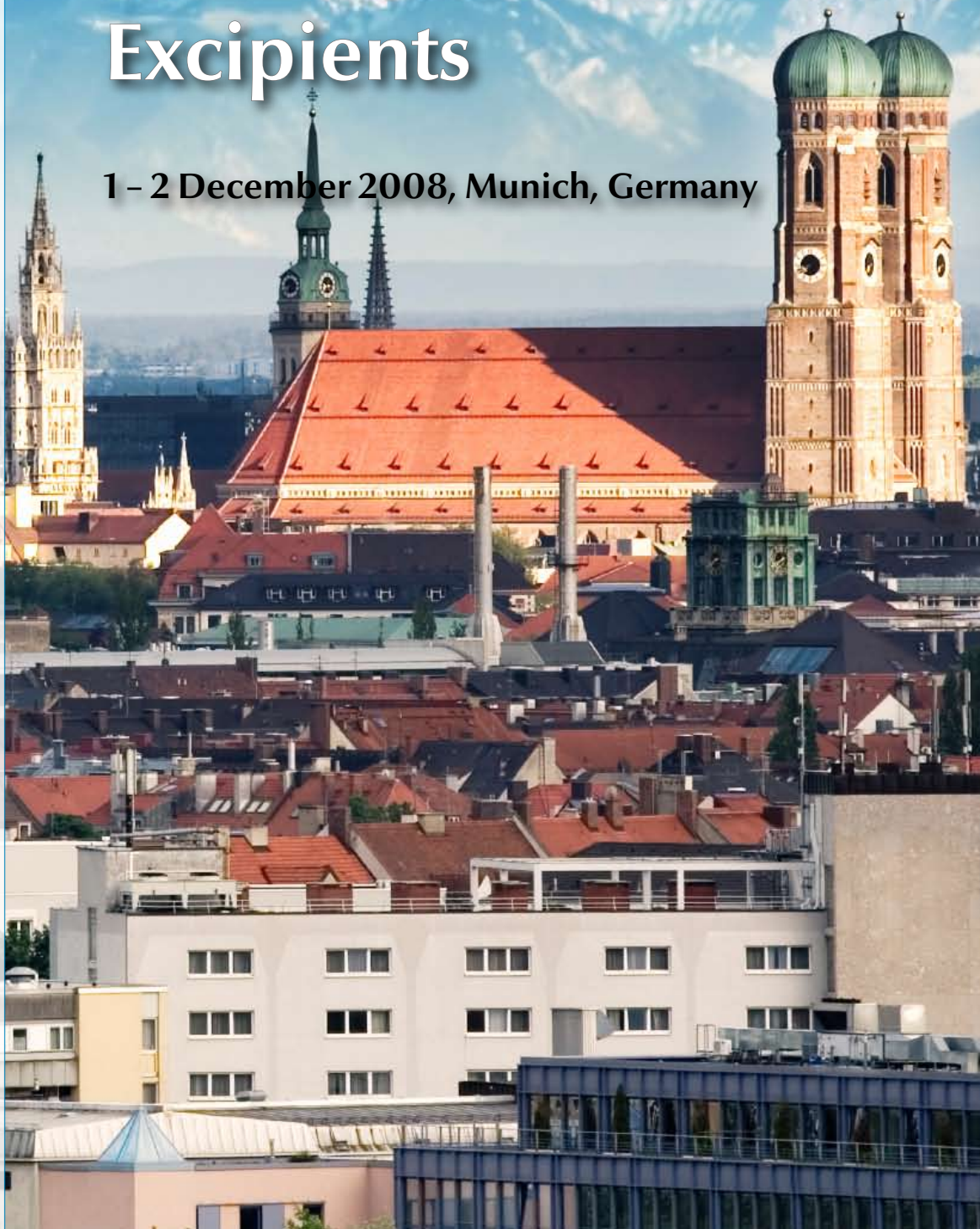
Jean-Claude Soule

Eli Lilly, France

European Conference on

Good Manufacturing Practices for Pharmaceutical Excipients

1 - 2 December 2008, Munich, Germany



European Conference on Good Manufacturing Practices for Pharmaceutical Excipients

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Welcome

Dear Colleagues,

With the implementation of the EU Directive 2001/83/EC into national law, all active pharmaceutical ingredients and the yet-to-be-defined Certain Excipients

used in pharmaceutical manufacturing, must be produced in compliance with current Good Manufacturing Practice (cGMP). However a series of incidents with major public health problems showed excipients of sub-standard quality or counterfeited excipients to be involved. Often the supply chains has many traders and brokers and is of considerable complexity. Currently regulation of excipients is limited and the legal enforceability is difficult. This situation has raised a debate about setting GMP, GDP and traceability requirements that are appropriate to excipients and do not simply mirror those developed for active pharmaceutical ingredients.

Our task at IPEC Europe and its sister organisations in America and Japan, is to continue to advocate better quality standards, appropriate regulation, and encourage innovation by protecting knowledge.

The IPEC Conference on Good Manufacturing Practices for Pharmaceutical Excipients provides an international forum for discussing new developments and recent initiatives of the major stakeholders.

We have invited speakers from EU, FDA and national authorities who will present updates on their recent and upcoming activities.

The conference provides time for networking with other colleagues and to benefit from exchanging information with industry and authority representatives.

I would like to invite you to this unique opportunity.

On behalf of IPEC Europe board,
Patricia Rafidison
Chair to IPEC Europe

Target Group

The conference addresses the Excipients supply chains for human and for veterinary medicines from the producer of Excipients to the user of Excipients. The conference is of particular interest for Qualified Persons of the Medicinal Product Manufacturers.

Programme

Monday, 1 December 2008

■ Update on EU GMP Guide Chapter 5 Revision

Katrin Nodop

EMA, United Kingdom

■ Update of the European Commission on Legal Initiatives concerning GMP

- Legal Proposal on Counterfeit Medicines
- Preparation of Excipients Legislation
- Regulatory Background
- Steps taken to date
- Results of online consultation

Sabine Atzor

European Commission, Enterprise and Industry Directorate-General, Belgium

■ FDA Update on the Control of Excipients

Steven Wolfgang, Edwin Rivera

FDA, USA

■ IPEC Guide as an appropriate guidance for Excipients manufacturers – Comparison to ICH Q7

Why excipient GMPs need to be different from APIs

- What is a relevant and appropriate GMP for excipients
- Why are aspects of EudraLex Vol 4 Part 2 (ICH Q7) not suitable for Excipients (comparison to IPEC-PQG Guide)
- The IPEC-PQG Guide as appropriate guidance

Kevin McGlue

Colorcon, United Kingdom

■ Design of an effective compliance programme for Excipients manufacturing

- Requirements and expectations
- Compliance programme concept
- Risk management
- Documentation
- Experiences and challenges

Stephan Peeters

Janssen Pharmaceutica NV, Belgium

■ Excipients certification – schemes, standards, value

- Why do we need excipients certification?
- A critique of existing excipient certification schemes
- Key requirements of any new scheme
- Update on the latest situation on the EFCG-IPEC excipient certification programme

Iain Moore

Croda Europe Ltd., United Kingdom

Tuesday, 2 December 2008

Parallel Sessions:

Auditing an Excipients Manufacturer

- Guidelines
- Audit process
- Different approaches
- Experiences / Typical findings

Stephan Peeters

Janssen Pharmaceutica NV, Belgium

Change control management

- Change of a packaging material
- Change of a supplier of starting materials
- Addition of a contract manufacturing site

Felicitas Guth

BASF SE, Germany

Excipients for use in parenteral products

- The parenteral plant, the main activities and expectations versus the suppliers
- The importance of the audit in the Certification process of suppliers
- The audit process (referential, plan & scope, report and follow-up of corrective action plan, ranking of the QMS)
- The main non-conformities and observations (exhaustive list of examples and pareto from 17 real audits)

Jean Claude Soule

Lilly France SAS, France

■ MHRA voluntary Inspection scheme

- Historical background
- Manufacturer's responsibilities
- Voluntary inspection programme
- Inspection findings

Bronwyn Phillips

MHRA, United Kingdom

■ Design and implementation of Risk-based Manufacturing strategies to meet Customers' GMP Expectations

- Summary of Risk Based Management
- Benefits of this approach for all
- Customers' GMP expectations
- What sort of strategy should you have?
- How should you aim to implement this?
- What are the key points to consider / stumbling blocks to avoid?
- How can this approach evolve and mature?

Richard Smalley

UCB Pharma S.A., Belgium

■ The role of quality agreements in Excipients supply

- Objectives and contents of Quality Agreements
- Negotiations of Quality Agreements – who should be involved?
- Quality Agreements with distributors and manufacturers – what to observe
- Quality Agreements and Commercial Agreements

Johanna Eisele

Evonik Röhm GmbH, Germany

■ Excipients pedigree – Repackaging, relabelling, recertification of excipients

- Why is « Panama » not that far from Europe than some people believe ?
- Excipient supply chain – a risk?
- What one needs to know about excipient pedigree
- Concepts to ensure product safety in the supply chain

Frank Milek

Aug. Hedinger GmbH & Co. KG, Germany

Speakers

Sabine Atzor

European Commission, Enterprise and Industry
Directorate-General, Belgium

Dr. Johanna Eisele

Evonik Röhm GmbH, Germany

Dr Felicitas Guth

BASF SE, Germany

Kevin McGlue

Colorcon, United Kingdom

Dr Frank Milek

Aug. Hedinger GmbH & Co. KG, Germany

Dr Iain Moore

Croda Europe Ltd., United Kingdom

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EMEA, United Kingdom

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UCB Pharma S.A., Belgium

Jean-Claude Soule

Eli Lilly France SAS, France

Steven Wolfgang

FDA, USA

Chairmen

Adrian L. Bone

Vice-Chair IPEC Europe, Belgium

Kevin McGlue

Colorcon, United Kingdom

Steering Committee

We would like to express our sincere gratitude to the members of the steering committee for developing the conference:

Gerhard Becker

Concept Heidelberg, Germany

Adrian L. Bone

Vice-Chair IPEC Europe, Belgium

Carole Capitaine

IPEC Europe, Belgium

Kevin McGlue

Colorcon, United Kingdom

Gianluca Ministrini

Roche, Switzerland

Oliver Schmidt

Concept Heidelberg, Germany

About IPEC

IPEC Europe, the International Pharmaceutical Excipients



Council Europe, is an association that serves the interests of producers, distributors and users of pharmaceutical excipients. Together with its sister associations, IPEC Americas and IPEC Japan (JPEC), the

Council is a member of TriPEC whose global membership extends to more than 200 companies.

IPEC Europe represents the views of its members to appropriate regulatory bodies (European Commission, EMEA, European Pharmacopoeia) and is recognised by Government agencies around the world as the voice of European producers and users of pharmaceutical excipients. Combined advocacy is essential to ensure introduction to the market of safe new excipients which meet globally accepted standards.

In 2007 IPEC Europe counted 70 full members, plus 3 associated and 2 co-opted members. Activities are organised through Committees or Working Parties the activities of which are communicated during the Annual General Meeting and in IPEC Europe newswashes, which are regularly posted on the News section of this site.

Registration

Monday, 1 December 2008, 09.00 h - 10.00 h

Conference

Monday, 1 December 2008, 10.00 h - 18.30 h

Tuesday, 2 December 2008, 08.30 h - 16.30 h

Venue

Holiday Inn Munich-Schwabing
Leopoldstraße 194
80804 München
Germany
Phone +49 (0)89 3 81 79-0
Fax +49 (0)89 3 81 79-888



Conference fees

Non-IPEC Members EUR 1,790.- per delegate plus VAT
IPEC Members EUR 1,611.- per delegate plus VAT
EU GMP Inspectorates EUR 895.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "VA 5693 Concept Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 30 September 2008. Early reservation is recommended.

Registration

You can either register via the attached reservation form, by E-Mail or by fax, or you can register online at www.ipeconference.org. Your registration will be confirmed by e-mail.

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:

Dr Gerhard Becker (Operations Director) at +49-62 21/84 44 65, or by e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Marion Grimm (Organisation Manager) at +49-62 21/84 44 18, or by e-mail at grimm@concept-heidelberg.de.

Conference Exhibition

Would you also like to present an exhibition stand? And have your company listed in the conference programme? Please contact Ms Marion Grimm at phone + 49-62 21 / 84 44 18, or per e-mail at grimm@concept-heidelberg.de.

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

European Conference on Good Manufacturing Practices for Pharmaceutical Excipients

1 - 2 December 2008, Munich, Germany

Please choose 1 out of 3 parallel sessions

First choice	Second choice	(in case your first choice is fully booked)
<input type="checkbox"/>	<input type="checkbox"/>	Session 1: Auditing an Excipients Manufacturer
<input type="checkbox"/>	<input type="checkbox"/>	Session 2: Change Control Management
<input type="checkbox"/>	<input type="checkbox"/>	Session 3: Excipients for Use in Parenteral Products

Dr Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

PO Number if applicable

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

General Terms of Business

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.

2. If you have to cancel entirely, we must charge the following processing fees:

Cancellation

- until 2 weeks prior to the conference 10 % of the registration fee.

- until 1 week prior to the conference 50 % of the registration fee.

- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee even if you have not made the payment yet. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed!).

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 250 events will be organised by CONCEPT HEIDELBERG.

Social Event

On 1 December 2008, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

