

**Europe's
leading
API Conference**

Authority Speakers:

Joe Famulare
FDA / USA

Susanne Keitel
European Directorate for the Quality of Medicines and HealthCare (EDQM)

Sabine Kopp
World Health Organisation (WHO)

Jacques Morenas
AFSSAPS, France

Moheb Nasr
FDA USA

Diana van Riet-Nales
National Institute for Public Health and Environment

EMA Representative
(invited)

Industry Speakers:

Tom Buggy
DSM Anti Infection

Marieke van Dalen
N.V. Organon, part of Schering Plough Corporation

William Heggie
Hovione

William H. Miele
Pfizer

Chris Oldenhof
DSM Anti Infection

Bruce Peel
Pfizer

Annemiek Rooijackers
N.V. Organon, part of Schering Plough Corporation

Jan Smeets
DSM Anti Infection

Remco Stol
N.V. Organon, part of Schering Plough Corporation

Li Ting
DSM Anti Infection

Hilde Vanneste
Janssen Pharmaceutica

John Webster
Pfizer

Neil Wilkinson
AstraZeneca



**11th APIC/CEPIC
European Conference on**

**Active
Pharmaceutical
Ingredients**

22 - 24 October 2008, Paris, France

GMP Conference

22 - 23 October 2008

**Regulatory Affairs
Conference**

23 - 24 October 2008

11th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

Objective

The APIC/CEFIC Conference on Active Pharmaceutical Ingredients is Europe's leading event. Many major stakeholders from Authorities and the Industry are each year joining this Conference. Speakers from FDA, EMEA, EDQM, WHO as well as Industry Experts will discuss the latest developments in the field of GMP and Regulatory Compliance.

The GMP requirements for APIs are clearly defined, particularly in the ICH countries. However, the compliance levels established at the various API sites worldwide may differ considerably. The two most prominent Regulatory Authorities in the western world are using different approaches to oversee the quality of APIs. While in Europe the manufacturer of the medicinal product – and on his behalf the Qualified Person – needs to assure API-GMP compliance the US FDA rely on their own inspections of the API manufacturers' sites. Both systems are currently trying to cope with the large and growing number of API manufacturers worldwide, part of which are appearing not to be in compliance with the international recognised standard ICH Q7 and/or with information submitted through registration dossiers. More and more information becomes available that both systems suffer from serious weaknesses.

These developments do not only influence the level playing field in the API markets. More importantly, APIs not manufactured under compliant conditions raise substantial safety concerns regarding the medicinal products that contain them. The establishment of an efficient and effective system for the oversight and enforcement of API compliance will become the key issue for the years to come.

The APIC/CEFIC Conference is the leading international forum for discussions on these important new developments. In addition, the conference will inform about the latest and to be expected regulatory developments by presentations of the major authority representatives. Moreover, 8 parallel sessions will provide the opportunity for an in-depth discussion of specific GMP and Regulatory Affairs topics.

Chairmen

Mr Anthony Storey, Pfizer, UK

Mr Matt Moran, Pharma Chemical Ireland

Ms Nessa Moyles, Pharma Chemical Ireland

Agenda

GMP Part

Wednesday, 22 October 2008

- **Implementation of Q10 – Inspector's expectation**
10.10 – 10.50 h
- **Q10 – Industry's expectation**
11.00 – 11.45 h
- **Third Party and Shared Third Party Audits as an option available to QPs of Manufacturing Authorisation Holders for Medicinal Products**
13.30 – 14.10 h
- **Update on APIC's Third Party Audit Programme and Auditing Guide**
14.20 – 14.35 h
- **Experience of an API Third Party Audit**
14.35 – 15.00 h
- **FDA's foreign inspections of API manufacturers**
15.40 – 16.20 h
- **Audits / Inspections from the APIC's point of view**
16.30 – 17.10 h
- **Panel Discussion** 17.20 – 18.00 h

GMP and Regulatory Affairs Part

Thursday, 23 October 2008

Parallel Sessions Part A

Session 1: Stability issues

Session 2: Risk-based approach for microbiological controls for non-sterile APIs

Session 3: New guidance on limits for metal catalysts and reagents

Session 4: Continuous processing

Parallel Sessions Part B

Session 5: ISPE guidance on bulk pharmaceuticals and cleaning validation

Session 6: PAT case study

Session 7: Confidentiality issues in DMF filing

Session 8: Recent issues on regulatory requirements

- **API aspects of FDA's 21st Century Quality Initiatives: A Progress Report**
13.15 – 14.00 h
- **ICH Q7 and the new Chinese SFDA GMP requirements for APIs: A comparison**
14.15 – 15.00 h
- **Update on CEP procedure**
15.45 – 16.30 h
- **The combat against counterfeit medicines/counterfeit APIs and the role of the HMA/WGEO**
16.45 – 17.30 h

Regulatory Affairs Part Friday, 24 October 2008

- **Global regulatory market**
08.30 – 09.45 h
- **Case study for a global change**
10.00 – 10.45 h
- **Changes and variations – state of play**
11.30 – 12.15 h
- **Japan change regulation**
12.30 – 13.15 h

Social Event



The social event has become a tradition and was well appreciated during the past conferences (in Brussels, Hamburg, Vienna, Barcelona, Budapest, Lisbon, Berlin, Prague and Warsaw). We will continue this tradition in Paris and invite all participants and speakers to an entertaining evening outside the hotel followed by a dinner.

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.

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
Marieke van Dalen, N.V. Organon, part of Schering Plough Corporation, The Netherlands
Rainer Fendt, BASF, Germany
Pieter van der Hoeven, CEFIC, Belgium
Henri Leblanc, Rhodia, France
Matt Moran, PharmaChemical Ireland
Nessa Moyles, PharmaChemical Ireland
Chris Oldenhof, DSM Anti-Infectives, The Netherlands
Luisa Paulo, Hovione, Portugal
Boris Pimentel, DSM Nutritional Products, Switzerland
Stephan Rosenberger, Lonza AG, Switzerland
Oliver Schmidt, CONCEPT Heidelberg, Germany
Anthony Storey, Pfizer, UK
Thomas Zwier, Pfizer, USA

Speakers include (as per 20 May 2008)

Tom Buggy, DSM Anti-Infectives
Marieke van Dalen, N.V. Organon, part of Schering Plough Corporation, The Netherlands
Joe Famulare, FDA / USA
William Heggie, Hovione
Susanne Keitel, European Directorate for the Quality of Medicines and HealthCare (EDQM)
Sabine Kopp, World Health Organisation (WHO)
William H. Miele, Pfizer
Jacques Morenas, AFSSAPS, France
Moheb Nasr, FDA, CDER-ONDQA, USA
Chris Oldenhof, DSM Anti Infectives
Bruce Peel, Pfizer
Diana van Riet-Nales, National Institute for Public Health and Environment, The Netherlands
Annemiek Rooijackers, N.V. Organon, part of Schering Plough Corporation, The Netherlands
Jan Smeets, DSM Anti Infectives
Remco Stol, N.V. Organon, part of Schering Plough Corporation, The Netherlands
Li Ting, DSM Anti-Infectives
Hilde Vanneste, Janssen Pharmaceutica, Belgium
John Webster, Pfizer
Neil Wilkinson, AstraZeneca

About CEFIC

CEFIC, the European Chemical Industry Council, is the Brussels-based organisation representing national chemical federations and chemical companies of Europe. All in all, CEFIC represents, directly or indirectly, more than 29,000 large, medium and small chemical companies in Europe, which employ about 1.7 million people and account for nearly one third of world chemical production.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Germany, Austria and Switzerland. This year, more than 240 events will be organised by CONCEPT HEIDELBERG.

Registration

Tuesday, 21 October 2008, 19.00 – 20.00 h or
Wednesday, 22 October 2008, 09.00 h - 10.00 h
Regulatory Affairs Part: Thursday, 23 October 2008, 8.00 - 8.30 h

Conference

Wednesday, 22 October 2008, 10.00 h – 18.00 h
Thursday, 23 October 2008, 08.30 h – 17.45 h
Friday, 24 October 2008, 08.30 h – 14.00 h

Venue

Novotel Paris Tour Eiffel
61, quai de Grenelle
75738 Paris Cedex 15
Phone +33 (0)1 40 58 20 00, Fax +33 (0)1 40 58 24 24

Fees

Book the GMP Part (22-23 October) or the Regulatory Affairs Part (23-24 October) separately for the price of € 1,680.- each. Or book all three conference days for the special price of € 1,990.-. The registration fee is payable in advance after receipt of invoice.

Discounts

APIC Members 10%, Inspectorates 25%, ECA Members 5%. **Please note that discounts cannot be combined!**

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 5660 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 10 September 2008. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.api-conference.org

Conference language

The official conference language will be English.

Organisation

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

For question regarding content:

Dr Gerhard Becker (Operations Director) at + 49 (0) 6221/84 44 65, or per e-mail at becker@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc.:

Ms Marion Grimm (Organisation Manager) at + 49 (0)6221/84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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 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 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)!**

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

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I want to take part in

- GMP Part (22-23 October 2008)**
 Regulatory Affairs Part (23-24 October 2008)
 All three conference days (22-24 October 2008)

Please choose 2 out of 8 parallel sessions (one choice in Session I and one in Session II)

First choice Second choice (in case your first choice is fully booked)

Parallel Session Part A

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Session 1: Stability issues |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 2: Risk based approach for microbiological controls for non sterile APIs |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 3: New guidance on limits for metal catalysts and reagents |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 4: Continuous processing |

Parallel Session Part B

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Session 5: ISPE guidance on bulk pharmaceuticals and cleaning validation |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 6: PAT case study |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 7: Confidentiality issues in DMF filing |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 8: Recent issues on regulatory requirements |

Mr Ms Title _____

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69007 Heidelberg
Germany

First name, surname

Company

APIC Member Inspectorate

Department

Important: Please indicate your company's VAT ID Number

P.O. Number if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-mail (please fill in)