

17<sup>th</sup> APIC/CEFIC European Conference on

# ACTIVE PHARMACEUTICAL INGREDIENTS

Vienna, Austria, 5 - 7 November 2014

GMP Conference

5 - 6 November 2014

Regulatory Affairs Conference

6 - 7 November 2014

## Authority Speakers:

**Robert Bream**  
*EMA; uk*

**Hélène Bruguera**  
*EDQM, France*

**Antony Fake**  
*WHO, Switzerland*

**Michel Keller**  
*Swissmedic, Switzerland*

**Theresa Mullin**  
*CDER, US FDA*

**Ewan Norton**  
*MHRA, United Kingdom*

**Takumi Ogawa**  
*PMDA, Japan*

**Russell Wesdyk**  
*CDER, US FDA*

## Industry Speakers

**Brian Corrigan**  
*Pfizer Biotech, Ireland*

**Marieke van Dalen**  
*Aspen Oss B.V., The Netherlands*

**Claudia Ferreira**  
*Hovione, Portugal*

**Samira Hadj-Sadok**  
*Roquette Freres, France*

**Karl Hensen**  
*Merck KGaA, Germany*

**Mechthild Sander**  
*Alfred E. Tiefenbacher, Germany*

**Moheb Nasr**  
*GSK, USA*

**Aloka Srinivasan**  
*Parexel International, USA  
formerly with FDA*

**Jan Smeets**  
*DSM Sinochem, The Netherlands*

**Florent Trouillet**  
*BASF, Switzerland*

**Dirk Overroedder**  
*Cilag, Switzerland*

**Hilde Vanneste**  
*Janssen Pharmaceutica, Belgium*

**Victoria Waddington**  
*Macfarlan Smith Limited  
A Johnson Matthey Company*

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# 17<sup>th</sup> APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

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## Objectives of the Conference

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, EMA, EDQM, National Authorities, from Industry and Industry Associations will discuss the latest developments in the field of GMP and Regulatory Compliance.

The GMP Conference, of which the final part is a Joint GMP & RA session, provides updates from the European and US Authorities on recent initiatives, activities and interpretations related to GMP compliance of API manufacturing. Hear from industry speakers their approaches and best practices on compliance related to the various existing and emerging aspects of API GMP.

The conference will be opened by a presentation about an update of FDA's current quality initiatives followed by a presentation about the new ICH Q&A document. Three more presentations are dedicated to the current EU Authority Inspection Programme, the aspects of contract manufacturing and GDP and an overview about the new Canadian API regulatory requirements.

The Joint GMP and Regulatory Affairs part of the conference will be rounded off by presentations about the implications of the ICH Q3D Guideline for the API industry, about an update from the EMA QWP and about the industry perspective of regulatory starting materials.

The specific GMP and Regulatory Affairs topics to be discussed in the Parallel Sessions will relate to current regulatory challenges.

The Parallel Sessions are no workshops. They are practically oriented and supposed to be highly interactive.

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## GMP Conference

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■ **10:00 – 10:15 h**

Conference Opening and Welcome



■ **10.15 – 11.10 h**

**The OPQ/OS Surveillance Initiative using Quality Metrics – An Update**

*Russell Wesdyk, CDER, US FDA*



■ **11.10 – 12.00 h**

**ICH Q7 Q&A – Why the need for a Q&A and will it benefit the industry?**

- Reason for a Q&A and not an amended guideline
  - The ICH Q7 Q&A process
  - Advantages the Q&A will give to the industry/authorities
- Michel Keller, Rapporteur of the ICH Q7 Q&A IWG, Swissmedic*



■ **13.30 – 14.20 h**

**Current overview of an EU Authority Inspection Programme**

- Overview of how GMP Inspections are being performed by an EU Inspector today and how the frequency of Inspections are set
- Are issues such as concerns over supply chain security, etc. changing the approach Inspectors take during and preparing for Inspections ?
- What are the types of observations now being observed. Has this changed with changes in recent regulatory requirement implementation and changes?
- Application of the use of the EudraGMP database and how it pertains to GMP non compliance statements?

*Ewan Norton, GMDP Inspector, MHRA*

# GMP Conference



## ■ 14.20 – 15.10 h

### **Contract manufacturing – views of contract receivers**

- The CMO Quality System (QS) Balancing Act
  - How to manage customer requirements / expectations
  - How to keep your QS manageable
- Be compliant, be effective and keep the customer happy
  - cGMPs,
  - Quality Agreements
  - Importance of good working relationships
- Tips for a successful collaboration
  - Review some sound rules
  - Communication flow
  - Audits
  - Documentation

*Claudia Ferreira, Head of QA Development Group, Hovione*

Coffee Break



## ■ 15.40 – 16.30 h

### **GDP for APIs – A challenge for multiple complex supply chains**

- Regulatory background for APIs
- GDP within supplier management
- Warehouse management according to GDP
- GDP for the global supply chain
- Experiences with authority inspections and customer audits
- Key topics for implementation

*Karl Hensen, Director Quality Assurance Chemicals, Merck KGaA*



## ■ 16.30 – 17.20 h

### **FDA's evolving focus on Quality: An inspection discussion**

- FDA/CDER approach to all-source surveillance of pharmaceutical quality
- A more interdisciplinary team-based approach to inspection
- More structured reports with more analyzable observations
- Extend range of observations beyond failures to recognize good quality control

*Theresa Mullin, CDER, US FDA*

Panel Discussion

### **Social Event**

The social event has become a tradition and was well appreciated during the past conferences (in Brussels, Hamburg, Barcelona, Budapest, Lisbon, Berlin, Prague, Warsaw, Paris, Venice, Munich, Madrid).

We will continue this tradition in Vienna and invite all participants and speakers to a **guided tour of Vienna and dinner at a beautiful Vienna restaurant.**



### **Austria Trend Royal Palace Hotel - next to Schönbrunn Castle**

**Take advantage of the special room rate of € 120,- for a single room per night incl. breakfast**



# Joint GMP and Regulatory Affairs Day

09.00 – 10.15 h

## Parallel Sessions, Part A



■ **Session 1:**  
**Current regulatory hurdles and opportunities, APIC's experiences**

- CEP latest developments
- ASMF latest developments
- Recent experiences with emerging markets



*Hilde Vanneste,  
CMC Regulatory Affairs, Janssen  
Pharmaceutica  
Victoria Waddington,  
Regulatory Compliance, Macfarlan Smith  
Limited A Johnson Matthey Company*



■ **Session 2:**  
**Insoluble Matter and Particles in API manufacturing**

- Expectations of customers and regulators
- Specifications and lab methods/ techniques for routine QC and investigational testing
- Investigation handling incl. risk assessments and QA disposition decision
- Tolerable vs. intolerable insoluble matter and particles
- Prevention & control strategy

*Dirk Overroedder,  
Head QA Chemicals, CILAG AG*

■ **Session 3:**  
**What with potential Genotoxic Impurities in APIs?**

- Potential Genotoxic Impurities
- Practical approaches to deal with PGIs
- Legal basis in a nutshell
- ICH M7
- Defining a control strategy
- Impact on API manufacturer
- Defining a control strategy at the level of API manufacturer

*To be named*

Coffee Break

10.45 – 12.00 h

## Parallel Sessions, Part B



■ **Session 4:**  
**Process Validation: a practical approach**

- Key requirements of New FDA/EU guidance
- How to integrate QbD and Q9 concepts in process validation
- BASF approach for critical parameter assessment
- How to deal with Continued Process Verification

*Florent Trouillet,  
Quality Department,  
BASF Pharma (Evionnaz)*



■ **Session 5:**  
**Biotech Comparability studies**

- Demonstrating comparability: biologics vs small molecule
- Methodologies and challenges in demonstrating comparability
- Regulatory application of comparability analysis (process changes, biosimilars)

*Brian Corrigan,  
Global CMC, Director BioTx CMC,  
Pfizer Biotech*



■ **Session 6:**  
**API Changes - for better or for worse?**

- Reasons for changes
- Changes in a global environment
- Practical examples
- Developments

*Marieke van Dalen,  
Global CMC RA CRS, Aspen Oss B.V.*

Lunch Break

# Joint GMP and Regulatory Affairs Day



■ 13.35 – 14.25 h

## Reflection on Current Pharmaceutical Quality and Regulatory Initiatives

- Current ICH Quality Initiatives
- Update on QbD implementation for APIs
- Regulatory and quality consideration of Continuous Manufacturing (CM)

*Moheb Nasr, Vice President CMC Regulatory Strategy, GSK*



■ 14.25 – 15.15 h

## Managing API supply chain – An EGA Perspective

- API Supplier qualification process: key elements
- GMP & GDP: the essential role of API manufacturers
- Regulatory maintenance of API documentation: a sore point

*Mechthild Sander, Alfred E. Tiefenbacher*

Coffee Break



■ 15.45 – 16.35 h

## ICH Q3D – industry's view on the guideline and expectation of API manufacturers

- Positive and negative points of the guideline
- How it relates to APIs
- Practical use of risk assessments versus testing; how and when do you need to test
- What industry requires of the authorities

*Samira Hadj Sadok, Regulatory Affairs, Roquette Freres*



■ 16.35 – 17.25 h

## EMA QWP update on definition of regulatory Starting Materials

*Robert Bream, Scientific Administrator, Human Medicines Evaluation Division, EMA*



■ 17.25 – 18.15 h

## The regulatory Starting Materials: an industry perspective

- Background of the issue
- The science based approach
- Practical examples

*Marieke van Dalen, Global CMC RA/CRS, Aspen Oss B.V.*

Panel Discussion

### Steering Committee

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

**Marieke van Dalen**

Aspen Oss, The Netherlands

**Rainer Fendt**

BASF, Germany

**Pieter van der Hoeven**

CEPIC, Belgium

**Matt Moran**

IBEC, Ireland

**Luisa Paulo**

Hovione, Portugal

**Boris Pimentel**

DSM Nutritional Products, Switzerland

**Anthony Storey**

Pfizer, UK

**Claude Vandebossche**

Ajinomoto-OmniChem, Belgium

**Hilde Vanneste**

Janssen Pharmaceutica, Belgium

**Gerhard Becker**

CONCEPT Heidelberg, Germany

**Oliver Schmidt**

CONCEPT Heidelberg, Germany



### Since 17 years - Europe's leading API Conference

There is no other API Conference in Europe which invites leading regulators from EU, FDA, WHO, EDQM, Japan etc. and from industry to discuss the latest GMP and regulatory developments. More than 200 delegates from more than 25 countries join this unique event every year.

# Regulatory Affairs Conference

## Objectives

After the several Regulatory topics presented during the second conference day, the RA conference will highlight latest developments of EDQM activities and initiatives, the WHO's pre-Qualification Programme and updates about Japanese regulatory requirements. A presentation about registration requirements for APIs in emerging countries will round off the Regulatory Affairs Conference programme.



### ■ 08.30 – 09.10 h

#### Latest developments of EDQM activities and initiatives

- International harmonisation of pharmacopoeias – where are we?
- Use of CEPs in Europe and worldwide
- International collaboration in the field of API inspections – current situation and opportunities

*Hélène Bruguera, Deputy Head/Division Certification of Substances, EDQM*



### ■ 09.10 – 09.50 h

#### WHO prequalification of APIs

- Why was API Prequalification introduced.
- What is the procedure for Prequalification
- Recent developments and issues

*Antony Fake, WHO*

Coffee Break



### ■ 10.20 – 11.00 h

#### FDA's Question-based Review for APIs in Applications for new drugs and generics

*Aloka Srinivasan, Parexel International, USA; formerly head of Drug Master File Team, CDER, FDA*



### ■ 11.00 – 11.40 h

#### New developments with respect to Japanese API regulation

*Takumi Ogawa, Office of New Drug IV, PMDA*



### ■ 11.40 – 12.20 h

#### Registration requirements for APIs in emerging countries

- How do API registration procedures work and what information is needed?
- What are the time lines?
- Is there any harmonization between the different countries?
- How to handle confidential information?
- What are the challenges in the emerging countries?

*Jan Smeets, International Regulatory Affairs, DSM Sinochem Pharmaceuticals*

### ■ 12.20 – 12.50 h

Panel Discussion

### ■ 12.50 – 13.00 h

Final Discussion, Closing Remarks

#### Important Information!

You will receive a USB memo stick when you register in Vienna.



Note: there will be **no print-outs** available during the conference.

**APIC**  
Active Pharmaceutical  
Ingredients Committee

#### APIC Guidance Documents

In addition to the PDF files of the presentations, all APIC Guidance documents will be available on this USB memo stick as well.

#### About APIC

APIC's membership consists of companies from different pharmaceutical industry sectors, all involved in the manufacture of APIs. This provides an ideal basis for developing and communicating a balanced, holistic view on API-related regulations and guidelines. APIC's focus is on worldwide Quality, Good Manufacturing Practice (GMP) and Regulatory matters relating to APIs and Intermediates. Through the years APIC has developed into a high-profile industry association with an excellent, worldwide reputation.

#### APIC's Best Practice Documents

APIC has developed many Best Practice Documents such as the ICH Q7 How-to-do Guide, the APIC Audit Programme, and Position Papers e.g. on API Starting Material, Post-approval Changes and many more.

## The Venue in Vienna

HOTEL PARK ROYAL PALACE – absolute gold standard



The newest hotel highlight of Vienna stands out in bright gold right next to the Technisches Museum (Technical Museum) and within eyeshot of Schloss Schönbrunn. Golden metal panels cover the façade of the hotel, which is equipped with the most modern amenities and state-of-the-art technology. A heavenly place for holiday makers and business travellers who are looking to be enchanted.



Our exclusive rooms are a true delight: exquisite Zebrano timber contrasts with sand-coloured elements, creating a beautiful visual effect in natural and indirect lighting. They also include fantastic views over Schloss Schönbrunn, the palace gardens and the hotel park.



## 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 250 events will be organised by CONCEPT HEIDELBERG.

## Lufthansa is Mobility Partner for all Concept Heidelberg Events

As an Concept Heidelberg course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the “Access to Event Booking” area you will also receive. This will take you into an online booking platform\* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming you at one of our next events – and we already wish you a pleasant flight!


\*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.



### GMP and GDP Compliance for Biotech APIs a pre-Conference Session on 4 November 2014

This pre-Conference Session ideally complements the subsequent 17th APIC/CEFIC Conference on Active Pharmaceutical Ingredients. If you register **both** for the pre-Conference Session „GMP and GDP Compliance for Biotech APIs“ and the 17th APIC/CEFIC Conference you will benefit from a **special rate of 690 €** (instead of 890 €) for the pre-Conference Session!

## Easy Registration

 **Reservation Form:**  
CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
69007 Heidelberg, Germany

 **Reservation Form:**  
+ 49 6221 84 44 34

 **e-mail:**  
info@concept-heidelberg.de

 **Internet:**  
www.api-conference.org

### Registration

Tuesday, 4 November 2014, 19.00 - 20.00 h

or

Wednesday, 5 November 2014, 9.00 h - 10.00 h

Regulatory Affairs Part:

Thursday 6 November 2014, 8.30 - 9.00 h

### Conference Date

Wednesday, 5 November 2014, 10.00 h - 18.00 h

Thursday, 6 November 2014, 09.00 h - 18.30 h

Friday, 7 November 2014, 08.30 h - 13.00 h

### Venue

Austria Trend Hotel Park Royal Palace Vienna

Schlossallee 8

1140 Vienna, Austria

Phone +43 1 8911 0

Fax +43 1 8911 9050



### Fees (per delegate plus VAT)

Book the GMP Part (5-6 November) or the

Regulatory Affairs Part (6-7 November)

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 %, ECA Members 5%,

Inspectorates 25 %.

### Accommodation

CONCEPT HEIDELBERG has reserved a

limited number of rooms in the conference

hotel. You will receive a room reservation

link when you have registered for the event.

Please use this link for your room reservation

to receive the specially negotiated rate for the

duration of your stay. Reservation should be

made directly with the hotel. 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](http://www.api-conference.org)

### Conference language

The official conference language

will be English.

### Organisation and Contact

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 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 at

grimm@concept-heidelberg.de

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

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CONCEPT HEIDELBERG

P.O. Box 10 17 64

Fax +49 (0) 6221/84 44 34

69007 Heidelberg

Germany

## 17<sup>th</sup> APIC/CEPIC European Conference on Active Pharmaceutical Ingredients

5-7 November 2014, Vienna, Austria

I want to take part in

- GMP Part** (5-6 November 2014)
- Regulatory Affairs Part** (6-7 November 2014)
- All three conference days** (5-7 November 2014)

Please choose 2 out of 6 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 Sessions I  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Session 1: Current regulatory hurdles and opportunities - APIC's experiences |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 2: Insoluble Matter and Particles in API manufacturing               |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 3: What with potential Genotoxic Impurities in APIs?                 |
|                          |                          | Parallel Sessions II   |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 4: Process validation: A practical approach                          |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 5: Biotech comparability studies                                     |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 6: API Changes - for better or for worse?                            |

- I also register for the pre-Conference Session "GMP and GDP Compliance for Biotech APIs" on 4 November 2014 at the special rate of 690 € plus VAT.**

Mr     Ms    Title \_\_\_\_\_

\_\_\_\_\_  
First name, surname

\_\_\_\_\_  
Company  APIC Member  ECA Member  Inspectorate

\_\_\_\_\_  
Department

\_\_\_\_\_  
Important: Please indicate your company's VAT ID Number

\_\_\_\_\_  
P.O. Number if applicable

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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 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)! (As of January 2012)