APIC Active Pharmaceutical Ingredients Committee a sector group of cefic

Europe's leading API Conference

18th APIC/CEFIC European Conference on

ACTIVE PHARMACEUTICAL INGREDIENTS

Amsterdam, The Netherlands
4 - 6 November 2015

GMP Conference
4 - 5 November 2015

Regulatory Affairs Conference
5 - 6 November 2015

Authority Speakers:

Hélène Bruguera
EDQM, France

Yong Seok Ko
NIFDS, South Korea

Anabela Marcal
Head of Compliance and Inspection Department EMA, United Kingdom

Mieke van der Meulen
Senior Inspector, Dutch Healthcare Inspectorate, The Netherlands

Ewan Norton
MHRA, United Kingdom

Jean-Louis Robert
Chairman of the EMA QWP, United Kingdom

Alex Viehmann
CDER, US FDA

Toru Yamaguchi
PMDA, Japan

Industry Speakers:

Wiebke Bähker
Merck, Germany

Denis Comeyne
Janssen Pharmaceutica, Belgium

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

Uwe Fischbeck
Merck, Germany

Betsy Fritschel
Johnson & Johnson, USA

George Hartong van Lokven
Aspen Oss B.V., The Netherlands

Koen Nauwelaerts
European Generic Medicines Association, Belgium

Luisa Paulo
Hovione, Portugal

Janeen Skutnik-Wilkinson
Biogen, USA

Anthony Storey
Pfizer, United Kingdom

Francois Vandeweyer
Janssen Pharmaceutica, Belgium

Hilde Vanneste
Janssen Pharmaceutica, Belgium

Lore Vignoli
Roquette Freres, France

Victoria Waddington
Macfarlan Smith Limited A Johnson Matthey Company, United Kingdom

Tim Watson
Pfizer, USA

18th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

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 industry's view on API Quality Metrics. The following presentations are dedicated to ways to reduce drug shortages, to the current Inspection findings with respect to data integrity, to the implementation of environmental requirements for API manufacturing and first experiences with the new ICH Q3D guideline about elemental impurities..

In the Joint GMP and Regulatory Affairs part of the conference you will hear presentations about regulatory requirements for registration of APIs in South Korea, quality and regulatory expectations of the API industry customers, the new GDP requirements, activities regarding ICH Q11 and an inspectorate's view on the manufacture of highly potent APIs.

The specific GMP and Regulatory Affairs topics to be discussed in the Parallel Sessions will relate to current regulatory challenges, special API related aspects of emerging markets, the manufacture of highly potent APIs, quality agreements and the implementation of the new Q/ Q&A document.

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

GMP Conference

- **An update on current FDA initiatives including Quality Metrics, Quality Culture and GDUFA**
  - Introducing CDER's new Office of Pharmaceutical Quality / Office of Surveillance
  - Overview and status of FDA's Quality Metrics Program
  - How quality metrics can support CDER surveillance
  - Overview of GDUFA program objectives and accomplishments

  Alex Viehmann, CDER, US FDA

- **API Quality Metrics – an Industry view**
  - Why FDA is focusing on Quality Metrics, where they get the authority to do so, how they say they will use the data collected
  - Current expectations for what data will be expected
  - Learnings from participation in pilots both internal and multi-company
  - Likely impact to API industry

  Betsy Fritschel, Regulatory Compliance, Johnson & Johnson, USA

- **What can the API Industry do to reduce drug shortages?**
  Anabela Marcal, Head of Compliance and Inspection Department EMA, United Kingdom

- **Current inspection findings: Data Integrity**
  - What is data integrity?
  - Why is it so important?
  - What are the authorities/Inspectors doing to identify this issue?
  - What can industry do to prevent such issues?

  Ewan Norton, GMDP Inspector, MHRA, United Kingdom

- **Risk based approach to implement environmental requirements for chemical API manufacturing**
  - Health Authorities regulations and expectations
  - Risk-based approach with focus on environmental contamination prevention
  - Structured on facility design, facility operations and environmental monitoring
  - Risk reduce measures

  Denis Comeyne, Senior Manager Engineering, Janssen Pharmaceutica, Belgium

- **ICH Q3D – what is the impact of this guideline to the API Industry?**
  - Why ICH Q3D isn't a testing guidance
  - What the guidance is and is not
  - What companies need to do to prepare for implementation
  - What this means (and doesn't mean) for API manufacturers
  - Suggestions for how companies should interact with their suppliers and customers

  Janeen Skutnik-Wilkinson, Biogen, USA

Panel Discussion

Joint GMP and Regulatory Affairs Day

Parallel Sessions, Part A

- **Session 1:**
  Quality Agreements
  - Quality Agreements between the API manufacturer and its customers: scope and legal requirements
  - Format and content of Quality Agreements
  - Successfully negotiating Quality Agreements: points for consideration
  - Further aspects (e.g. maintenance, multiple sites/parties)
  - APIC Quality Agreement Guideline and Templates

  Wiebke Bähker, Global Regulatory Management, Merck KGaA, Germany

- **Session 2:**
  Post approval change management protocol
  - Guidelines on post approval change management protocols
  - Benefit for Industry
  - Practical implications

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

- **Session 3:**
  GMP compliant manufacture of highly potent APIs
  - General concepts and technical details.
  - Hygienic design piping class for chemicals
  - Special reactor design
  - Isolator technologies
  - Cleaning of equipment

  Speaker to be named

Coffee Break

Parallel Sessions, Part B

- **Session 4:**
  Q7 Q&A – how to implement
  - Overview of the ICH Q7 Q and A document
  - Benefits of the document to Industry
  - Good practices/how to do & interpret the Q and A document
  - Question and Answer open discussion session how to implement Q7/current concerns and expectations

  Anthony Storey, Pfizer, United Kingdom
  Francois Vandeweyer, Janssen Pharmaceutica, Belgium

- **Session 5:**
  Emerging Markets – current regulatory requirements
  - Regulatory mapping
  - Manufacturers' experiences sharing
  - Current and forthcoming challenges

  Lore Vignoli, Regulatory Affairs, Roquette Freres, France

- **Session 6:**
  Current regulatory issues and hurdles
  - CEP latest developments
  - ASMF latest developments
  - Recent experiences with emerging markets

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

Lunch Break

- **Registration requirements for APIs in South Korea**
  Yong Seok Ko, Deputy Director, National Institute of Food and Drug Safety Evaluation (NIFDS), South Korea

- **Quality and regulatory expectations of the API industry customers**
  - API supply chain Regulatory issues : Concerns regarding increasing GMP information in the regulatory dossier
  - Distribution of API : GDP
  - Expectations regarding the implementation of ICH Q3D on metal impurities
  - API starting materials

  Koen Nauwelaerts, European Generic Medicines Association, Belgium

- **Highly potent APIs: an inspectorate's view**
  - Which highly active substances can be handled in the same building/facility/plan?
  - How much containment is needed?
  - What should a risk analysis contain?
  - How should exposure measurements be carried out?
  - What has to be considered for the cleaning of equipment?

  Mieke van der Meulen, Coordinating/Specialist Senior Inspector, Dutch Healthcare Inspectorate, The Netherlands

- **Update on activities regarding ICH Q11**
  - Why the need for a IWG Q11 activity?
  - Why the concern over the definition of a RSM
  - Work of the ICH Q11 IWG and expected outcomes
  - What this activity will bring to industry and authorities
  - What are the concerns for an industry perspective

  Tim Watson, CMC Advisory Office, Pfizer, USA

- **How to implement the new GDP requirements**
  - The new EU GDP Guideline: What is actually new?
  - Experiences with the implementation of GDPs for APIs
  - Customer and authority expectations
  - APIC How-to-do Document on GDPs

  Uwe Fischbeck, Director Quality Assurance, Merck KGaA, Germany

Panel Discussion

Regulatory Affairs Conference

Objectives
After several Regulatory topics will have been presented during the second conference day, the RA conference will highlight key aspects of the ICH Q12 guideline, the latest developments of EDQM activities and initiatives, procedures for post-approval changes in Japan and registration requirements of APIs in Brazil. A presentation about the activities of the EMA Quality Working Party with focus on aspects of Quality by Design will round off the Regulatory Affairs Conference programme.

- **Procedures for post-approval changes in Japan**

  Toru Yamaguchi, Reviewer, Office of Generic, PMDA, Japan

- **Last development of Brazilian regulation for Active Substances**
  - Upcoming API registration process
  - Focus on RDC 60 and requirements for active substances

  Speaker to be named

- **ICH Q12 – current status of life cycle management**
  - Scope of the guideline and major objectives
  - Impact on the industry – benefits
  - Regulatory implications
  - Key aspects of the guideline
  - Next steps

  Luisa Paulo, Hovione, Portugal

- **Working towards harmonisation and regulatory convergence – the experience of EDQM**
  - Update on the Ph. Eur activities including new monographs, international harmonisation, good pharmacopoeial practice
  - Implementation of new ICH guidelines in the CEP procedure (ICH Q11, Q3D, M7)
  - Worksharing initiatives for ASMF and CEPs (EU ASMF, IGDRP)
  - The EDQM inspection programme and international collaboration in the area of API inspections

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

- **EMA QWP – aspects of Quality by Design**

  Jean-Louis Robert, Chairman of the EMA QWP, United Kingdom

Final Discussion, Closing Remarks

The Venue in Amsterdam

Mövenpick Hotel Amsterdam City Centre

Spectacular views over the city and vistas over the river IJ are just some of the highlights at Mövenpick Hotel Amsterdam City Centre, just 20 minutes from Schiphol Airport. With its fantastic location in the heart of the city centre, our 4-star hotel is also within walking distance of Amsterdam's historical centre, its central station and many museums.

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, Vienna). We will continue this tradition in Amsterdam and invite all participants and speakers to a boat trip on the Amstel including dinner on the boat.

Steering Committee

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

Rainer Fendt, BASF, Germany
Nessa Fennelly, IBEC, Ireland
Pieter van der Hoeven, CEFIC, Belgium
Luisa Paulo, Hovione, Portugal
Anthony Storey, Pfizer, UK
Hilde Vanneste, Janssen Pharmaceutica, Belgium
Gerhard Becker, CONCEPT Heidelberg, Germany
Oliver Schmidt, CONCEPT Heidelberg, Germany

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.

Lufthansa is Mobility Partner for all Concept Heidelberg Events

As a 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!

Important Information!
You will receive a USB memo stick when you register in Amsterdam.

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.

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

GMP-compliant Manufacture of Biotech APIs – an Update
a pre-Conference Session on
3 November 2015

This pre-Conference Session ideally complements the subsequent 18th APIC/CEFIC Conference on Active Pharmaceutical Ingredients.

If you register **both** for the pre-Conference Session „GMP compliant manufacture of Biotech APIs – an Update" and the 18th 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, 3 November 2015, 19.00 – 20.00 h or
Wednesday, 4 November 2015, 09.00 - 10.00 h
Regulatory Affairs Part:
Thursday, 5 November 2015, 8.30 - 9.00 h

Conference Date
Wednesday, 4 November 2015,
10.00 – 18.00 h
Thursday, 5 November 2015,
09.00 – 18.00 h
Friday, 6 November 2015,
09.00 – 13.00 h

Venue
Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11
1019 BR Amsterdam, The Netherlands
Phone: +31 (0)20 519 12 00
Fax: +31 (0)20 519 12 390

Fees (per delegate plus VAT)
Book the GMP Part (4-5 November) or the Regulatory Affairs Part (5-6 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**

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
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For question regarding content:
Dr Gerhard Becker (Operations Director)
at + 49 (0) 6221/84 44 65, or at
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For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager)
at + 49 (0)6221/84 44 18, or at
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69007 Heidelberg
Germany

18th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients
4-6 November 2015, Amsterdam, The Netherlands

I want to take part in
- ☐ **GMP Part** (4-5 November 2015)
- ☐ **Regulatory Affairs Part** (5-6 November 2015)
- ☐ **All three conference days** (4-6 November 2015)

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
☐	☐	Session 1: Quality Agreements
☐	☐	Session 2: Post approval change management protocol
☐	☐	Session 3: GMP compliant manufacture of highly potent APIs
		Parallel Sessions II
☐	☐	Session 4: Q7 Q&A – how to implement
☐	☐	Session 5: Emerging Markets – current regulatory requirements
☐	☐	Session 6: Current regulatory issues and hurdles

☐ **I also register for the pre-Conference Session "GMP-compliant Manufacture of Biotech APIs – an Update" on 3 November 2015 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

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (please fill in)

General terms and conditions
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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).

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