APIC Active Pharmaceutical Ingredients Committee a sector group of cefic

Europe's leading API Conference

NEW

Pre-Conference Session „**ICH Q3D** Guideline for Elemental Impurities" on 5 November 2013

16th APIC/CEFIC European Conference on ACTIVE PHARMACEUTICAL INGREDIENTS

Madrid, Spain, 6 – 8 November 2013

GMP Conference
6 - 7 November 2013

Regulatory Affairs Conference
7 - 8 November 2013

Authority Speakers:

Hélène Bruguera
EDQM, France

Rosimeire Pereira Alves da Cruz
ANVISA, Brazil

Juan Gao
CFDA, China

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

Manuel Ibarra Lorente
AEMPS, Spain

Christa Wirthumer-Hoche
AGES, Austria

Dulcelina Mara Pereira Said
ANVISA, Brazil

Industry Speakers

Pamela Berger
DSM Nutritional Products, Switzerland

Malcolm Berry
GSK, United Kingdom

Lígia Brás
Hovione, Portugal

Graham Cook
Pfizer, United Kingdom

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

Oliver Grosche
Novartis, Switzerland

Holger von der Heydt
Boehringer Ingelheim, Germany

Frithjof Holtz
Merck, Germany

Moheb Nasr
GSK, USA

Jolanta Pawlowska
Polpharma, Poland

Rudy Peeters
Janssen Pharmaceutica, Belgium

Karsten Diehl
BASF, Germany

Cindy Shen
Roche-Genentech, China

Francois Vandeweyer
Janssen Pharmaceutica, Belgium

Victoria Waddington
Macfarlan Smith Limited A Johnson Matthey Company, UK

16th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

Objective 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 aspect of API GMP.

The conference will be opened by a presentation about Challenges and opportunities within the existing regulatory environment followed by an update of FDA's current inspection activities.

The authorities' and industry's view of EU Directive 2011/62 on Falsified Medicines will be shared with the audience Two more presentations are dedicated to the importance of a control strategy for APIs and to the relevance of the provisions of the ICH Q11 guideline for generics APIs.

Last but not least there will be an update on EDQM's activities, the question of starting materials definition and the implications of the new ICH Q3D guidance on metal impurities. The Joint GMP and Regulatory Affairs part of the conference will be rounded off by presentations about Canadian GMP and regulatory requirements for APIs and an update on Chinese GMP regulations.

The specific GMP and Regulatory Affairs topics to be discussed in the Parallel Sessions will relate to current regulatory challenges, GDP for APIs and the application of control technologies in the API industry.

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

GMP Conference

- **10:00 – 10:15 h**
  Welcome Address and Introduction

- **10:15 - 11:05 h**
  Continual improvement – Regulatory Challenges and Opportunities
  - Continual improvement and CMC lifecycle
  - Current business and regulatory challenges
  - The role of ICH and global harmonization initiatives
  - How can we move forward?

  Moheb Nasr, Vice President CMC Regulatory Strategy, GSK

- **11:05 - 12:00 h**
  FMD, is it helping to protect patient safety? Overall Industry view
  - Overview of medicines manufactured using non EU APIs
  - Trends of quality problems since implementation date
  - Counterfeiting issues - sources- trends -identification of blackspots
  - Overview of border issues - seizures - prevention of imports of APIs
  - Trends in importation of APIs in mixtures - in dosage forms
  - Details on observed incidences of patient safety events e.g. Heparin type events
  - Overview of non API aspects to Directive - packaging, serialisation etc
  - What can API industry do to enhance patient safety?
  - Role of Council of Europe/EDQM - update on IMPACT initiative

  Graham Cook, Sr. Director, Process Knowledge/Quality by Design
  Pfizer

Lunch Break

■ **13:30 - 14:20 h**
Control strategy for APIs
- What are the Regulatory Drivers to establish a Control Strategy ?
- What is a Control Strategy Summary (CSS)?
- Common Terminology – The Basis for CSS
- How is Criticality of Quality Attributes, Material Attributes and Process Parameters being assessed?
- How is the Business Process for CSS set up?

Holger von der Heydt, Head of Coordination Quality Concepts, Global Dept. Launch Process Control & Compliance, Boehringer Ingelheim

■ **14:20 - 15:10 h**
Q11 for generics APIs
- QbD versus traditional development approach on Generic products
  - Pros and cons of both approaches
  - Criteria to define the best approach
  - Challenges in chemical synthesis process
- Relation between material attributes, CPPs and CQAs
- Selection of SRM
- Control strategy how should it be defined
- Impact on submissions
  - Some practical examples
  - Process validation approach

Jolanta Pawlowska, Head of Technology Development Department of R&D, Polpharma

Coffee Break

■ **15:40 - 16:30 h**
FMD, authorities roll out of the directive
- Overview of total imports of APIs into EU based on survey conducted via HMA group - including market breakdown
- Overview of white list or equivalent exporting countries - issues that may have arisen during assessment
- Implementation timelines for each member state - difficulties experienced meeting these - evidence of shortages
- Overview of application of waiver 2 - where inspections conducted – issues
- Overview of acceptance of existing GMP certificates including sites inspected against CEP via EDQM programme
- Assessment of written GMP declarations – issues
- Overview of issues that have arisen through local MS inspections of drug product sites - including QP issues

Manuel Ibarra Lorente, Pharmaceutical Inspection and Enforcement Department, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

■ **16:30 – 17:20 h**
Current Activities and Trends at US FDA – Personal Perspective
To be named

Panel Discussion

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, Warsaw, Paris, Venice, Munich).

We will continue this tradition in Madrid and invite all participants and speakers to an entertaining evening outside the hotel followed by a dinner.

Joint GMP and Regulatory Affairs Day

08:30 - 09:45 h
Parallel Sessions, Part A

■ **Session 1:**
Current regulatory hurdles and opportunities, APIC's experiences
- EDQM latest developments
- Starting materials, tips and tricks
- Japan experiences
- ASMF assessment initiative

Marieke van Dalen,
Global CMC RA/CRS, Aspen Oss B.V.,
Victoria Waddington,
Regulatory Compliance, Macfarlan Smith Limited A Johnson Matthey Company

■ **Session 2:**
The new EU GDP Draft Guide and the APIC 'How to do' Guide on GDP for APIs
- Key requirements of the new GDP Draft Guideline
- Comparison of the "How to do" Guide with other documents/ guidelines
- Scope and content
- How to use the document
- Practical examples/case study

Frithjof Holtz, Director Advocacy Pharm Chemicals Solutions, Merck
Karsten Diehl, Nutrition & Health, GMP Compliance Manager Pharma Ingredients & Services, BASF

■ **Session 3:**
Application of process analytical technology in the API industry
- PAT at development stages of a QbD-based development
- PAT as part of the Control Strategy in a GMP environment
- Practical examples of PAT implementations at a commercial scale in a GMP environment

Lígia Brás,
PAT Group, Hovione

Coffee Break

10:15 - 11:30 h
Parallel Sessions, Part B

■ **Session 4:**
Improvement of the ASMF Guideline: Industry point of view
- Timing / Implementation / Missing transition period
- Formal requirements vs. current practice:
  - ASMF submission (once vs. multiple submissions per country)
  - Procedure number - tracking and history?
  - MAH expectations

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

■ **Session 5:**
API definition – API Mixtures
- Should API Mixtures (API/auxiliary substance(s) mixtures) be excluded from the CEP/ASMF procedure?
- What are the implications for the API Mixture producer?
- What are the implications for the finished product manufacturer?
- Issues to be discussed
- Recent experiences with authorities
- Current arguments accepted and proposed

Pamela Berger,
Regulatory Affairs Manager,
DSM Nutritional Products

■ **Session 6:**
Continuous processing from fume-hood to factory – how can it be done?
- The evolution of GSK approach to continuous processing over the last decade
- GSK projects' selection criteria
- GSK approach to QbD and PAT for continuous processing
- The impact of raw materials
- Simplification of the engineering and the process to deliver an overall robust, intensified and viable process

Malcolm Berry, GSK

Lunch Break

Joint GMP and Regulatory Affairs Day

13.05 – 13.55 h
Update from EDQM
- Update on EU pharmacopoeia
- Update on anti-counterfeit activities and implementation of FMD at EDQM
- Update on certification procedure and changes
  - Update on policies for evaluation of CEPs
  - Update on inspections

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

13.55 – 14.45 h
Starting materials, APIC's view on RSM definition
- Criteria for defining SM
- Provision of "pre-SM" information and how to handle changes to this information
- Quality management of SM manufacture
- Application of risk management principles

Rudy Peeters, Janssen Pharmaceutica

Coffee Break

15.15 – 16.05 h
ICH Q3D – Metal Impurities
- Status of the ICH Q3D guideline, similarities and differences with the EU Metal Catalysts guideline
- The classification system of heavy metals and metal catalysts in the proposed guideline, thresholds
- What is the link with the EP and USP monographs, which are being elaborated?
- Scope of the guideline, only new products?, what about changes and variations?,
  what about excipients and pre-blended active substances?
- Implications to the API industry – additional requirements – analytical work required – costs
- Timelines until adoption. What is the time to be implemented in the EU?

Oliver Grosche,
Novartis Pharma Global Technical Operations, Basel, Switzerland

16.05 – 16.55 h
How to do Document - a guidance for Implementation of ICH Q7
Francois Vandeweyer, Janssen Pharmaceutica

16.55 – 17.45 h
The supervision of APIs in China
- The update of the reorganization of CFDA
- The action taken by CFDA and Chinese API manufacturers to EU counterfeit directive 62.
- The approach and feature of the supervision on APIs in China

Juan Gao, CFDA, Shanghai, China
Cindy Shen, Roche-Genentech, Shanghai, China

Panel Discussion

Steering Committee

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

Boris Pimentel,
DSM Nutritional Products,
Switzerland

Pamela Berger,
DSM Nutritional Products,
Switzerland

Anthony Storey,
Pfizer, UK

Rainer Fendt,
BASF, Germany

Hilde Vanneste,
Janssen Pharmaceutica, Belgium

Stefan Rosenberger,
Lonza, Switzerland

Pieter van der Hoeven,
CEFIC, Belgium

Gerhard Becker,
CONCEPT Heidelberg, Germany

Oliver Schmidt,
CONCEPT Heidelberg, Germany

Regulatory Affairs Conference

Objectives
After the several Regulatory topics presented during the second conference day, the RA conference will highlight the move towards centralised review of API information in connection with the ASMF guideline, the activities of the EMA Quality Working Party regarding APIs and the current regulatory requirements for APIs in Brazil. A presentation about global harmonised regulatory approaches will round off the Regulatory Affairs Conference programme.

- **08.30 – 09.20 h**
  Worksharing initiative of ASMF assessment reports
  - Revision of the ASMF Guideline
  - EU numbering system for ASMFs
  - First experience with the pilot project
  - Improvement of consistency?

  Christa Wirthumer-Hoche,
  Chair of the Joint Working Group on ASMF procedures and
  Head of Institute Marketing Authorisation & Lifecycle Management, AGES

- **09.20 – 10.10 h**
  Update from the European Medicines Agency – Quality Working Party (QWP) regarding APIs
  - Different topics depending on the latest regulatory developments

  Jean-Louis Robert,
  Chairman of the EMA QWP

Coffee Break

- **10.40 – 11.30 h**
  Brazil current API regulatory requirements
  - How does the registration of Active Pharmaceutical Ingredients in Brazil work?
  - Normative Instruction No 15
  - References to the Active Pharmaceutical Ingredient file in Brazil
  - Confidentiality of data in Brazil
  - Handling changes in Brazil

  Rosimeire Pereira Alves da Cruz, Dulcelina Mara Pereira Said,
  ANVISA, Brazil

- **11.30 – 12.20 h**
  The global harmonized regulatory opportunity: rethink regulatory approaches
  - Is global harmonisation needed for industry and/or regulators?
  - Support and constraints of guidelines in harmonisation
  - Support and results over time of Organisations involved in harmonisation
  - Is there a path forward?

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

- **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 Madrid.

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

The Venue in Madrid

Meliá Castilla, much more than just a hotel

The Meliá Castilla is considered one of the most emblematic hotels in Madrid, with an appealing blend of perfectly balanced classic and contemporary styles, where peace and urban life are accomplices to delight our guests. The excellent location, a few minutes from Paseo de la Castellana, 15 minutes from Barajas airport and IFEMA exhibition centre, near Chamartín train station and the Real Madrid Santiago Bernabéu football stadium, makes the Meliá Castilla the perfect choice for your visit to Madrid.

Take advantage of the special room rate: Single room € 140,- per night incl. breakfast, plus 10% VAT

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 APIC

APIC is one of CEFIC's Sector Groups, comprising producers of active pharmaceutical ingredients (APIs) and intermediates in Europe. For this reason APIC considers itself to be a very important stakeholder in new EU Regulations and Guidelines related to APIs and intermediates. Our 64 members are located all over Europe and include three national associations: AFAQUIM (Spain), PHARMACHEMICAL IRELAND (Ireland) and SICOS (France).

APIC's key objectives are:

- To promote the use of compliant APIs in medicinal products to ensure patient safety
- To represent the interests of pharmaceutical and chemical companies producing APIs and intermediates in Europe by being recognized experts who advance and influence the global GMP and Regulatory environment.

APIC is very active in communicating and monitoring developments of the active pharmaceutical ingredients industry as well as in defending the APIC views and positions on proposed legislation, regulations and guidelines.

The new
"ICH Q3D Guideline for Elemental Impurities"
a pre-Conference Session on
5 November 2013

This event is designed as a pre-Conference Session. The key aspects and requirements of the new ICH Guideline will be discussed in detail. This pre-Conference Session ideally complements the subsequent 16th APIC/CEFIC Conference on Active Pharmaceutical Ingredients.
If you register both for the pre-Conference Session on ICH Q3D and the 16th APIC/CEFIC Conference you will benefit from a **special rate of 690 €** for the pre-Conference Session!

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 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.

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, 5 November 2013, 19.00 – 20.00 h or
Wednesday, 6 November 2013, 09.00 - 10.00 h
Regulatory Affairs Part:
Thursday 7 November 2013, 8.00 - 8.30 h

Conference Date
Wednesday, 6 November 2013, 10.00 h – 18.00 h
Thursday, 7 November 2013, 08.30 h – 18.00 h
Friday, 8 November 2013, 08.30 h – 13.00 h

Venue
Melia Castilla
Hotel and Convention Center
Capitán Haya, 43
28020 Madrid, Spain
Phone: +34 (0)91 567 50 77
Fax: +34 (0)91 567 50 66

Conference language
The official conference language will be English.

Fees
Book the GMP Part (6-7 November) or the Regulatory Affairs Part (7-8 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.
*per delegate + VAT

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 form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate (single room € 140 per night, incl. breakfast, plus 10% VAT) for the duration of your stay. Reservation should be made directly with the hotel not later than 5 October 2013. 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

Organisation and Contact
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For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager)
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If the bill-to-address deviates from the specification to the right, please fill out here:

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69007 Heidelberg
Germany

16th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients
6-8 November 2013, Madrid, Spain
I want to take part in

☐ **GMP Part** (6-7 November 2013)
☐ **Regulatory Affairs Part** (7-8 November 2013)
☐ **All three conference days** (6-8 November 2013)

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: Current regulatory hurdles and opportunities – APIC's experiences
☐	☐	Session 2: The new EU GDP Draft Guide and the APIC 'How to do' Guide on GDP for APIs
☐	☐	Session 3: Application of process analytical technology in the API industry
		Parallel Sessions II
☐	☐	Session 4: Improvement of the ASMF Guideline: Industry point of view
☐	☐	Session 5: Drug substance preparation
☐	☐	Session 6: Continuous processing from fumehood to factory – how can it be done

☐ **I also register for the pre-Conference Session "ICH Q3D - Guideline for Elemental Impurities" 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

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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)