APIC Active Pharmaceutical Ingredients Committee a sector group of cefic

Europe's leading API Conference

19th APIC/CEFIC European Conference on

ACTIVE PHARMACEUTICAL INGREDIENTS

Barcelona, Spain
23 - 25 November 2016

GMP Conference
23 - 24 November 2016

Regulatory Affairs Conference
24 - 25 November 2016

Authority Speakers:

Hélène Bruguera
EDQM, France

Brendan Cuddy
EMA, United Kingdom

Graeme McKilligan
MHRA, United Kingdom

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

Industry Speakers:

Richard M. Bonner
United Kingdom

Tom Buggy
DSM Corporate Operational Audit, The Netherlands

Graham Cook
Pfizer, United Kingdom

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

Ralf Gengenbach
Gempex, Germany

Roisin Hickey
Hovione, Ireland

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

Graca Mata
Hovione, Portugal

Rudy Peeters
Janssen Pharmaceutica, Belgium

Colin Rienewerf
Piramal, United Kingdom

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

Helen Xue
Intertek Chemicals & Pharmaceuticals China

19th 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 recent authorities' 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 how to manage an effective Quality Management system followed by a presentation about the Qualified Person's role on ensuring GMP-compliant manufacture of APIs. The following lectures are dedicated to the consequences arising from non GMP-compliant manufacture of APIs, the FDA's Quality Metrics program, quality risk management in global API supply chains and data integrity issues.

In the Joint GMP and Regulatory Affairs part of the conference you will hear presentations about the ICH Q11 regulatory starting materials Q&A, the new ICH Q12 guideline and its impact on post approval changes, combined play of GMP and regulatory aspects in the regulatory dossier and an update on EDQM's activities.

The specific GMP and Regulatory Affairs topics to be discussed in the Parallel Sessions will relate to quality aspects of starting materials, GMP compliant API facility design and data integrity issues as well as current regulatory hurdles, practical experiences concerning GDUFA and ICH Q3D in connection with API manufacturers' responsibilities.

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

GMP Conference

- **How to manage an effective Quality Management System**
  - QMS - what does an inspector expect?
  - Areas of deficiency in current inspections
  - What industry should be doing to improve QMS and Quality culture

  Graeme McKilligan, MHRA, United Kingdom

- **Quality (Risk) management in Global API Supply Chain**
  - GxP regulations and guidelines to be considered
  - Characteristics and challenges of global supply chains
  - Managing logistic service providers
  - How to ensure Supply Chain transparency (incl. customer expectations)
  - Transport validation and risk assessments on temperature deviations

  Tom Buggy, Auditor MSQ, DSM Corporate Operational Audit, The Netherlands

- **An update on Quality Metrics (QM) program**
  - Program overview – update
  - How API industry may help FDA
  - New guideline version
    - How different is it from the 1st draft?
    - How and when API industry will be involved
    - Which QM API industry will report?
    - How the QM now defined will fit the FDA program purpose
  - Implementation program

  <speaker to be named>

- **Data Integrity – How big the issue is?**
  - How do the Inspectors assess sites/companies for data integrity either in a paper system and IT systems
  - Concerns and implications
    - Are Inspectors finding more area of concern or is industry reacting to the need to control data integrity?
    - What are the trends
  - Does industry fully understand data integrity
  - How far inspectors expect industry go to mitigate the (possible) data Integrity issues
  - What are the potential consequences of companies exposed to data integrity issues

  <speaker to be named>

- **What keeps QPs awake at night from an API perspective**
  - What are the regulatory expectations of a QP with respect to APIs - is this clear to all interested parties
  - What concerns have QPs on ensuring GMP compliant APIs
  - What can the QP and the API Industry do to ensure compliance
  - How does the globalisation of the API Industry impact QPs and what are the concerns
  - What can both parties do to ensure supply chain is robust and does not impact drug shortages

  Richard M. Bonner, ECA, formerly with Eli Lilly, United Kingdom

Open Q&A Session

Joint GMP and Regulatory Affairs Day

Parallel Sessions, Part A

- **Session 1:**
  Quality expectation of starting materials
  - Guidelines
  - HA expectations and recent observations
  - GMPs for Starting materials (manufacturing / analytical)
  - Auditing of Starting materials
  - Q&A

  Francois Vandeweyer, Janssen Pharmaceutica, Belgium

- **Session 2:**
  GMP requirements on API facility design
  - What GMPs are really required for facility design?
  - Which guidelines and standards can help?
  - Which basic design concepts you should follow
  - What are "state of the art" solutions?
  - What are the most common design problems?

  Ralf Gengenbach, gempex Co. Ltd., Germany

- **Session 3:**
  Regulatory Hurdles and Opportunities
  Graca Mata, Hovione, Portugal
  Victoria Waddington, Regulatory Compliance, Macfarlan Smith Limited A Johnson Matthey Company

Coffee Break

Parallel Sessions, Part B

- **Session 4:**
  ICH Q3D – the role and responsibilities of API manufacturers
  - What is the responsibility of the API industry in supporting product license holders achieve compliance with ICH Q3D?
  - What are the expectations of our customers?
  - How/what is an acceptable risk assessment for APIs with regard to ICH Q3D? (With alternative approaches)
  - Experiences from the API industry – good and bad

  Colin Rienewerf, Piramal, United Kingdom

- **Session 5:**
  GDUFA practical experiences
  - GDUFA overview
  - Fees
  - DMF Initial Completeness assessment
  - New Guidance under GDUFA

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

- **Session 6:**
  Data integrity – Industry perspective
  - Key areas of concern
  - How to mitigate data integrity issues
  - Examples of measures taken
  - Experience with inspections

  Roisin Hickey, Hovione, Ireland

Lunch Break

- **ICH Q11 regulatory starting materials Q&A – does it help industry?**
  - Overview of the ICH Q11 Q and A
  - Will we have a global harmonisation view on definition of a registered starting material
  - Impact of the Q and A to the API industry
  - Pros and cons of the Q and A document

  Rudy Peeters, Janssen Pharmaceutica, Belgium

- **ICH Q12 – impact on Post Approval Changes**
  - Current status
  - Concerns and implications
  - How it will impact the post approval changes
  - What type of changes will benefit
  - How much the industry will benefit from the guideline

  Graham Cook, Pfizer, United Kingdom

- **Combined play of GMP and regulatory aspects in the regulatory dossier**
  - What GMP requirements are currently part of the dossier?
  - How did the requirements evolve over time?
  - How does this impact the patient and industry?
  - Is the regulatory dossier the best place?

  Hilde Vanneste, Janssen Pharmaceutica, Belgium

- **Update on current EDQM activities and initiatives**
  - News in the Ph. Eur
  - Implementation of ICH Q3D in the Ph. Eur and on CEPs
  - Worksharing and regulatory convergence for the assessment of the quality of APIs
  - International collaboration in inspections of API manufacturers

  Hélène Bruguera, Head of the Certification Division, EDQM

Open Q&A Session

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 how API registration works in emerging countries followed by an overview about regulatory filing expectations and new Pharmacopoeia requirements in China. Presentations about the development of impurities specifications over the years and aspects of APIs changes assessment will round off the Regulatory Affairs Conference programme.

- **Consequences of non GMP compliance**
  - Non GMP compliant APIs – what can be the impact to API manufacturers?
  - What is causing licence withdrawals and drug shortages from non GMP compliant APIs ?
  - How is EU industry informed that such a supplier is non-compliant?
  - What can the API Industry do to prevent drug shortages?
  - What can the authorities do to aid API companies in ensuring supply chain is maintained?

  Brendan Cuddy, Compliance and Inspection Sector, EMA, United Kingdom

- **API registration in Emerging Markets : current industries' experiences**
  - How do API registrations work?
  - What are the challenges in the emerging countries?
  - The APIC Task Force outcomes

  Lore Vignoli, Regulatory Affairs, Roquette Freres, France

- **Progress of China Pharmaceutical Regulation and Practice in Ensuring Quality and Safety**
  - Regulatory Filing expectations
    - Process and requirements
    - Organizational structure
    - What's new (recent changes)
    - Future expectations
  - Chinese Pharmacopeia
    - Recent changes
    - How to comply (acceptable transition process?)
    - Availability English version?
    - Expectations

  Helen Xue, Intertek Chemicals & Pharmaceuticals China

- **Development of Impurity specifications over the years**
  - Guidelines: from the past to the future
  - The importance of technology innovation
  - Assessment by the Competent Authorities
  - Impact in the Pharmaceutical Industry

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

- **Assessment of APIs Changes**
  - Current situation
  - Generic APIs: a regulatory nightmare
  - Desired situation

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

Final Discussion, Closing Remarks

The Venue in Barcelona

Crowne Plaza Barcelona - Fira Center Hotel

Crowne Plaza Barcelona - Fira Center Hotel is set in the heart of Montjuic, one of the most cultural areas of the city. Located between the famous Plaza de Espana and Gran Via Avenue, visit the nearby Montjuic Magic Fountains, Olympic Stadium and Montjuïc Castle. The excellent location is only a 25 minutes' drive from Barcelona's International Airport and with the metro station Plaza Espana being a short walk away, Crowne Plaza Barcelona – Fira Center is the perfect choice.

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).

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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 – otherwise the booking platform window will not open.

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

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, CEFIC, Belgium
Graca Mata, Hovione, Portugal
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.

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

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.

The ICH Q7 Questions & Answers Document – an Update on GMP for APIs –

a pre-Conference Session on
22 November 2016

This pre-Conference Session ideally complements the subsequent 19th APIC/CEFIC Conference on Active Pharmaceutical Ingredients.

If you register **both** for the pre-Conference Session „The ICH Q7 Questions ans Answers Document - an Update on GMP for APIs" and the 19th APIC/CEFIC Conference you will benefit from a **special rate of 690 €** (instead of 890 €) for the pre-Conference Session!

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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, 22 November 2016, 19.00 – 20.00 h or
Wednesday, 23 November 2016, 09.00 - 10.00 h
Regulatory Affairs Part:
Thursday, 24 November 2016, 8.30 - 9.00 h

Conference Date
Wednesday, 23 November 2016,
10.00 – 18.00 h
Thursday, 24 November 2016,
09.00 – 18.30 h approx
Friday, 25 November 2016,
08.30 – 13.30 h

Venue
Crowne Plaza
Barcelona – Fira Center
Av. Rius i Taulet, 1-3
E-08004 Barcelona
Phone: +34 93 426 22 23
Fax: +34 93 425 50 47

Fees (per delegate plus VAT)
Book the GMP Part (23-24 November) or the Regulatory Affairs Part (24-25 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 %.
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 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
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69007 Heidelberg, Germany
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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

19th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients
23-25 November 2016, Barcelona, Spain
I want to take part in

- ☐ **GMP Part** (23-24 November 2016)
- ☐ **Regulatory Affairs Part** (24-25 November 2016)
- ☐ **All three conference days** (23-25 November 2016)

Please choose 2 out of 6 parallel sessions (one choice in Session I and one in Session II)

Parallel Sessions I

- ☐ Session 1: Quality expectation of starting materials
- ☐ Session 2: GMP requirements on API facility design
- ☐ Session 3: Regulatory Hurdles and Opportunities

Parallel Sessions II

- ☐ Session 4: ICH Q3D - the role and responsibilities of API manufacturers
- ☐ Session 5: GDUFA practical experiences
- ☐ Session 6: Data integrity - Industry perspective

☐ **I also register for the pre-Conference Session "The ICH Q7 Questions & Answers Document - an Update on GMP for APIs" on 22 November 2016 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 %.

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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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