Join us and celebrate the 20th APIC Conference and 25 years of APIC/CEFIC!

20th APIC/CEFIC European Conference on

ACTIVE PHARMACEUTICAL INGREDIENTS

Berlin, Germany

25 – 27 October 2017

Authority Speakers:

- Hugo Bonar
  HPRA, Ireland
- Hélène Bruguera
  EDQM France
- Sven-Erik Hillver
  MPA, Sweden
- Anabela Marcal
  EMA, United Kingdom
- Keith McDonald
  MHRA, United Kingdom
- Yusuke Okada
  PMDA, Japan
- Jean-Louis Robert
  Co-opted CHMP member, ICH Q12 EU topic lead, United Kingdom

Industry Speakers:

- Raymond Boyse
  Eli Lilly, Ireland
- Marièke van Dalen
  Aspen Oss B.V., The Netherlands
- Manuel Figueiredo
  Hovione, Portugal
- Betsy Fritschel
  Johnson & Johnson, USA
- Daniella van Gauwbergen
  Janssen Pharmaceutica, Belgium
- Patrick Lefèvre
  PCAS, France
- Martijn Klop
  Synthon, The Netherlands
- Koen Nauwelaerts
  Medicines for Europe, Belgium
- Mechthild Sander
  Alfred E. Tiefenbacher, Germany
- Christian Scheidl
  Novartis, Germany
- Paul Stockbridge
  Biopharm Consulting, United Kingdom
- Michael Toward
  Johnson Matthey MacFarlan Smith, United Kingdom
- Francois Vandeweyer
  Janssen Pharmaceutica, Belgium
- Hilde Vanneste
  Janssen Pharmaceutica, Belgium

GMP Conference

25 – 26 October 2017

Regulatory Affairs Conference

26 – 27 October 2017
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 industry’s experiences with Quality Metrics followed by a presentation about the current status of the FDA/EMA Mutual reliance initiative. The following lectures are dedicated to the Regulatory Starting Materials, APIC’s revised GDP How to do Guide, industry’s experiences with continuous processing and counterfeiting APIs.

In the Joint GMP and the Regulatory Affairs part of the conference you will get an update on EDQM’s activities and hear presentations about the ICH Q11 Q&A from a health authority perspective, the current status of ICH Q12 and its benefit from the regulator’s perspective, the current status of generic drug review in Japan, the QWP’s and the industry’s point of view regarding ICH Q3D, API variations and generic industry’s experience, and case studies on post approval changes.

The specific GMP and Regulatory Affairs topics to be discussed in the Parallel Sessions will relate to practical experiences with ASMF assessment/ worksharing, APIC’s revised Quality Agreement Guideline and Template and practical experiences with non EU/US authorities inspections. Further topics are dedicated to data integrity issues in the analytical environment and how to prevent them, APICs experience with supporting documentation for API filings in Emerging Countries and GMP requirements for biotech vs. biological APIs.

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

Programme

GMP Conference - Wednesday, 25 October 2017

Quality Metrics - Industry experiences so far
Betsy Fritschel, Johnson & Johnson, USA
- ISPE feedback on the Quality metrics initiative implementation
- Quality metrics reporting – benefits for the industry and patients
- Constraints, difficulties, challenges to the industry

FDA/EMA Mutual Recognition Agreement: current status
Anabela Marcal, Head of Committees and Inspections Department EMA, United Kingdom
- Background of the initiative
- Hurdles (to) overcome
- Advantages for Industry

Regulatory Starting materials: a GMP perspective
François Vandeweyer, Janssen Pharmaceutica, Belgium
- Introduction / Recent trends
- Regulatory Guidelines and papers
- Issues for Starting material selection
- HA expectations
- APIC TF
- GMPs for Starting materials (manufacturing/analytical)
- Auditing of Starting materials
- Q&A

GDP for APIs: the revised APIC How to do guide
Daniella van Gauwbergen, Janssen Pharmaceutica, Belgium
- Legal framework of GDP for API and customers’ expectations
- How to comply with GDP requirements - API industry recommendations (focus on the How To Do Document)
- How API manufacturer may address GDP compliance for product shipped under non-controlled conditions (Focus on position paper and product supply chain routes qualification strategy)

Elements of a Successful Control Strategy for Continuous API Production
Raymond Boyse, Eli Lilly, Ireland
- First commercial continuous manufacturing facility in the EU for small molecule APIs
- Technical, engineering, environmental and health and safety considerations
- Regulatory issues and challenges
- Future trends

Important Information
You will receive a USB memo stick when you register in Berlin. Note: there will be no print-outs available during the conference.

APIC Guidance Documents
Every participant will receive a USB memo stick which contains all APIC Guidance documents including the revised “GDP for APIs How to do document” and the revised “Quality Agreement Guideline”. 
Counterfeiting APIs: welcome to the real world!
Hugo Bonar, HPRA, Ireland

- The development of workable enforcement powers to face the counterfeit/falsified challenges
- Current trends facing public health from counterfeiting/falsification
- Challenges from criminal elements – organised or white collar crime
- What are regulators/law enforcement doing to meet the challenges
- How can regulatory and industry better cooperate to prevent, detect and challenge counterfeiters

Open Q & A Session
Take the opportunity to ask about and discuss your topics of interest.

Parallel Sessions - Thursday, 26 October 2017

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

**SESSION PART I**

**Session 1:**
ASMF assessment/worksharing: practical experience
Martijn Klop, Synthon, The Netherlands
- How the European ASMF worksharing procedure works
- Update on the current status
- Practical experiences of an ASMF holder

**Session 2:**
Quality agreements: revised APIC guideline and template
Patrick Lefèvre, PCAS, France
- Quality Agreements between API and drug manufacturers: legal/regulatory requirements and customer expectations
- The revised APIC guideline and template: what has changed?
- How to best use the APIC standard template?

**SESSION PART II**

**Session 4:**
APICs experience with supporting documentation for API filings in Emerging Countries
Michael Toward, Johnson Matthey MacFarlan Smith, United Kingdom
Manuel Figueiredo, Hovione, Portugal
- Emerging Countries Interest Group – What is it and what do we do?
- Supporting documentation required when using a CEP
- Supporting documentation required when using a DMF

**Session 5:**
Data integrity: how to prevent problems in the analytical environment
Christian Scheidl, Novartis Technical Operations - Quality, Germany
- What does data integrity mean? (mainly for ALCOA principles, data integrity continuum)
- Legal framework for data integrity requirements
- What is needed to ensure data integrity (validation/qualification of CS and automated systems, quality system, good documentation practices, quality culture….)
- How to address data integrity issues within the laboratory from simple equipment to computerized systems

**Coffee Break**

**Session 6:**
GMP requirements for biotech vs. biological APIs
Paul Stockbridge, Biopharm Consulting, United Kingdom
- Applying biotech regulations to biologicals
- Is separate guidance needed for extraction products?

**Lunch Break**
Objectives

After several Regulatory topics will have been presented during the second conference day, the RA conference will highlight key aspects of ICH Q3D global implementation and the generic industry’s view as well as the QWP’s perspective. Presentations about the Generic industry’s experience with API variations and case studies of post approval changes will round off the Regulatory Affairs Conference programme.

ICH Q3D global implementation: the generic industry’s view

Mechthild Sander, Alfred E. Tienf abc h er, Germany
- How is industry progressing with the implementation of the ICFH Q3d guideline?
- What are the main hurdles to overcome?
- How can the flow of information between API manufacturers, Finished product manufacturers and Marketing authorisation holders be optimised?

ICH Q3D – QWP’s point of view

Sven-Erik Hillver, Medical Products Agency, Sweden
- How does the risk assessment work in practice?
- What is the information to be provided by API Industry to their customers
- What will be covered in the next Q3D & what is the status?

Generic industry’s experience with API variations

Koen Nauwelaerts, Medicines for Europe, Belgium
- API variations as a significant part of the total amount of variations
- What can regulators and industry do to decrease the regulatory burden?
- How can predictability of API variations be created?

Post approval changes: a case study

Marieke van Dalen, Global CMC RA/CRS, Aspen Oss B.V., The Netherlands
- Challenges with a global product
- Timelines
- Implementation of the change

Open Q & A Session

Take the opportunity to ask about and discuss your topics of interest.

Open Q & A Session

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The Venue in Berlin

Steigenberger Hotel am Kanzleramt

Right outside of the main train station, in sight of the Federal Chancellery, you will find the Steigenberger Hotel Am Kanzleramt. Many places of interest are within walking distance, including the Platz der Republik (approx. 850 m) and the Brandenburg Gate (approx. 1.5 km).

The city hotel offers 339 air-conditioned and soundproofed rooms, including 24 luxurious suites. Thanks to the modern and comfortable room facilities, you can benefit from a flat-screen TV, safe, minibar, coffee and tea-making facilities, seating area and desk.

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!

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

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
- Matt Moran, IBEC, Ireland
- Luisa Paulo, Hovione, Portugal
- Vicky Waddington, United Kingdom
- 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.

Elemental Impurities and CEPs

Requirements for new CEP applications, already existing CEPs and CEP revisions

a pre-Conference Session on 24 October 2017

This pre-Conference Session ideally complements the subsequent 20th APIC/CEFIC Conference on Active Pharmaceutical Ingredients.

If you register both for the pre-Conference Session „Elemental Impurities and CEPs – Requirements for new CEP applications, already existing CEPs and CEP revisions“ and the 20th APIC/CEFIC Conference you will benefit from a special rate of 690 € (instead of 890 €) for the pre-Conference Session!
Registration
Tuesday, 24 October 2017, 19.00 – 20.00 h or Wednesday, 25 October 2017, 09.00 h - 10.00 h

Regulatory Affairs Part:
Thursday, 26 October 2017, 8.30 - 9.00 h

Conference Date
Wednesday, 25 October 2017, 10.00 h – 17.20 h
Thursday, 26 October 2017, 09.00 h – 17.20 h
Friday, 27 October 2017, 08.30 h – 13.20 h

Venue
Steigenberger Hotel am Kanzleramt
Ella-Trebe-Str. 5
10557 Berlin
Germany
Tel.: +49 030 – 74 07 43 0
Fax.: +49 030 - 740743 999

Fees (per delegate plus VAT)
Book the GMP Part (25-26 October) or the Regulatory Affairs Part (26-27 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 %,
ECA Members 5 %,
Inspectorates 25 %.
Please note that discounts cannot be combined!

Accommodation
CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. 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

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25 - 27 October 2017, Berlin, Germany
I want to take part in
☐ GMP Part (25-26 October 2017)
☐ Regulatory Affairs Part (26-27 October 2017)
☐ All three conference days (25-27 October 2017)

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

Parallel Sessions I
☐ Session 1: ASMF assessment/ worksharing: practical experience
☐ Session 2: Quality agreements: revised APIC guideline and template
☐ Session 3: Inspections by non EU / US authorities: practical experiences

Parallel Sessions II
☐ Session 4: APICs experience with supporting documentation for API filings in Emerging Countries
☐ Session 5: Data integrity: how to prevent problems in the analytical environment
☐ Session 6: GMP requirements for biotech vs. biological APIs

☐ I also register for the pre-Conference Session “Elemental Impurities and CEPs – Requirements for new CEP applications, already existing CEPs and CEP revisions” at the special rate of 690 € plus VAT.

☐ Mr ☐ Ms Title _______

Company ☐ o APIC Member ☐ o ECA Member ☐ o Inspectorate

Department

Important: Please indicate your company’s VAT ID Number
P.O. Number if applicable

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City Zip Code Country

Phone / Fax

E-mail (please fill in)

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be transferred to third parties. Further information: www.gmp-compliance.org/eca_privacy.html. I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.