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

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

Manuel Figueiredo
Hovione, Portugal

Betsy Fritschel
Johnson & Johnson, USA

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

APIC active pharmaceutical ingredients committee
25 years of promoting patient safety

a sector group of

cefic

20th 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 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 feed-back 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 Guidances 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

Speaker from APIC Task Force (confirmed)

- 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)

Continuous processing: industry experience

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

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.

Social Event

Wednesday, 25 October 2017

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

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 3: Inspections by non EU / US authorities: practical experiences

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

- Inspections from non-ICH countries are increasing
- What are the typical topics
- Are there special things to consider?

Coffee Break

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

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

Joint GMP and Regulatory Affairs Day - Thursday, 26 October 2017

Update on EDQM activities

Hélène Bruguera, EDQM France

- The work programme of the Ph. Eur and how to take part in it
- Recent developments for Ph. Eur texts
- The CEP procedure: how to build a good CEP application according to most recent requirements
- The EDQM inspection programme for APIs manufacturers, where are we today?

Current Status of Generic Drug Review in Japan

Yusuke Okada, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

- Japanese approach for CMC description method
- Handling of starting materials based on Q11
- Change Control and marking description reflecting
- Expected outcome of Q12
- Generic CTD compilation

ICH Q11 Q&A, a health authority perspective

Keith McDonald MHRA, United Kingdom

- Development and manufacture of drug substance – both synthetic and biological origin – according to ICH Q11
- Selection and justification of starting materials
- Further clarification and guidance by the ICH Q11 Q&A document
- Selection of the starting material for a synthetic manufacturing process and its impact on industry and regulators
- The objective of the ICH Q11 Q&A
- Status update on the Q&A document.

ICH Q12: Benefit and Challenges from a Regulatory Point of View

Jean-Louis Robert, Co-opted CHMP member, ICH Q12 EU topic lead, United Kingdom

Open Q & A Session

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

Regulatory Affairs Conference - Friday, 27 October 2017

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. Tiefenbacher, 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?

Open Q & A Session

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

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

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 Conferenceyou will benefit from a **special rate of 690 €** (instead of 890 €) for the pre-Conference Session!

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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

Conference language
The official conference language will be English.

Organisation and Contact
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69007 Heidelberg
Germany

20th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients
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 _____

First name, surname

Company o APIC Member o ECA Member o 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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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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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).

German law shall apply. Court of jurisdiction is Heidelberg.

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