

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

20<sup>th</sup> APIC/CEFIC European Conference on

# ACTIVE PHARMACEUTICAL INGREDIENTS

Berlin, Germany  
25 – 27 October 2017

## Authority Speakers:

**Julia-Verena Bacher**  
*AGES, Austria*

**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*

**Valérie Guilbaut**  
*Novacyl, France*

**Patrick Lefèvre**  
*PCAS, France*

**Martijn Klop**  
*Synthon, The Netherlands*

**Koen Nauwelaerts**  
*Medicines for Europe, Belgium*

**Moheb Nasr**  
*GSK, USA*

**Mechthild Sander**  
*Alfred E. Tiefenbacher, Germany*

**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

# 20<sup>th</sup> 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 and industry's perspective, the QWP's point of view regarding ICH Q3D, API variations and generic industry's experience, FDA's Division of Lifecycle APIs assessment of DMFs 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
- Constrains, difficulties, challenges to the industry



#### FDA/ EMA Mutual reliance initiative: current status

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

- Background of the initiative
- Hurdles (to) overcome
- Advantages for Industry, once signed



#### 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

## 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.



## Open Q & A Session

Take the opportunity to ask 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 3: Inspections by non EU / US au- thorities: 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 suppor- ting 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

Valérie Guilbaut, Novacyl, France (APIC Task Force on Data Integrity)

- 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

Julia-Verena Bacher, AGES, Austria

- 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

*H el ne 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?



### ICH Q12: What would be the benefit for the industry?

*Moheb Nasr, GSK, USA*

- Industry perspective on how ICH Q12 will impact on the post approval change management across product lifecycle.
- Which are the regulatory tools and enablers that will promote innovation and continuous improvement?



### 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 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 FDA's Division of Lifecycle APIs assessment of DMFs 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?



### 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?



### 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



### 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 and discuss your topics of interest.*

## 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!





Reservation Form:  
+ 49 6221 84 44 34



e-mail:  
info@concept-heidelberg.de



Internet:  
www.api-conference.org

## 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](http://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  
info@concept-heidelberg.de  
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## For question regarding content:

Dr Gerhard Becker (Operations Director)  
at + 49 (0) 6221/84 44 65, or at  
becker@concept-heidelberg.de

## For questions regarding reservation, hotel, organisation etc.:

Ms Marion Grimm (Organisation Manager)  
at + 49 (0)6221/84 44 18, or at  
grimm@concept-heidelberg.de

If the bill-to-address deviates from the  
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Germany

## 20<sup>th</sup> APIC/CEPIC 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 \_\_\_\_\_

APIC Member  ECA Member  Inspectorate

Department \_\_\_\_\_

Important: Please indicate your company's VAT ID Number \_\_\_\_\_

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Street / P.O. Box \_\_\_\_\_

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## 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  
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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.

**Privacy Policy:** By registering for this event,  
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ask for the modification, correction or deletion of my data at any  
time via the contact form on this website.