

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

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

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, APIC's 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

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

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 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 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

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

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?



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?



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.

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

Conference language

The official conference language will be English.

Organisation and Contact

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For question regarding content:

Dr Gerhard Becker (Operations Director)
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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
specification to the right, please fill out here:

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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 _____

APIC Member ECA Member Inspectorate

Department _____

Important: Please indicate your company's VAT ID Number _____

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Street / P.O. Box _____

City _____

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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 %.

CONCEPT HEIDELBERG reserves the right to change the
materials, instructors, or speakers without notice or to cancel
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notified as soon as possible and will receive a full refund of fees
paid. CONCEPT HEIDELBERG 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. 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,
I accept the processing of my Personal Data. Concept Heidelberg
will use my data for the processing of this order, for which I
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ask for the modification, correction or deletion of my data at any
time via the contact form on this website.