APIC Active Pharmaceutical Ingredients Committee a sector group of cefic

Europe's leading API Conference

Authority Speakers:

Peter Bachmann
CMDh Chair and BfArM, Germany'

Hélène Bruguera
EDQM France

David Cockburn
EMA, United Kingdom

Anne Hayes
IMB, Ireland

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

Vibhakar Shah
Office of Compliance, CDER, US FDA

Qing Shen
Shanghai FDA, China

Industry Speakers:

Tom Buggy
DSM Sinochem Pharmaceuticals Netherlands B.V., The Netherlands

Marieke van Dalen
MSD, The Netherlands

Veronique Davoust
EFPIA, Belgium

Robert A. Dollinger
Novacyl, USA

Melissa Figgins
Sandoz, USA

Georges France
Novartis, Switzerland

Frithjof Holtz
Merck, Germany

Luc Janssens
Janssen Pharmaceutica, Belgium

Moheb Nasr
GSK, USA

Fred Ward
Janssen Pharmaceutica, Ireland

Jan Smeets
DSM Sinochem Pharmaceuticals Netherlands B.V., The Netherlands

Aloka Srinivasan
Parexel International, USA

Anthony Storey
Pfizer, United Kingdom

Hilde Vanneste
Janssen Pharmaceutica, Belgium

Guy Villax
Hovione, Portugal

15th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

7 - 9 November 2012, Budapest, Hungary

GMP Conference
7 - 8 November 2012

Regulatory Affairs Conference
8 - 9 November 2012

Media Partner:
"The Gold Sheet" IPQ

Objective 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.

GMP Conference

The GMP Conference, of which the final part is a Joint GMP & RA session, provides updates from the European and US Authorities on recent 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 aspect of API GMP.

As usual, FDA will present the latest developments in connection with the increasing demand of inspections of API manufacturing sites. FDA's new fee act GDUFA which will have a major impact to the Generic industry will also be discussed.

The importance of a Quality Culture and unique role of the QP with respect to API quality oversight will be other key topics. Two more presentations are dedicated to the relevance of cleaning validation and to the assessment of API starting materials.

The State of Play of Implementation of EU Directive 2011/62 on Falsified Medicines will be shared with the audience by EMA.

Last but not least there will be an update on the new ICH Q11 guidance and the latest regulatory developments in China with relevance to the global API business.

The specific GMP and Regulatory Affairs topics to be discussed in the Parallel Sessions will relate to the new residual metal guidance, to Good Distribution Practices Systems and to GMPs for early phase clinical biotechnology products. Moreover quality culture aspects at CMOs, special API requirements in connection with OTCs and APIC's experiences with recent GMP and regulatory developments concerning starting materials and APIs will be discussed.
The Parallel Sessions are no workshops. They are practically oriented and supposed to be highly interactive.

Programme

- **10:10 - 11:05 h**
  Development and Implementation of risk-based Control Strategy of APIs: A view from the Innovator Pharma Industry
  - Control strategy and role of specifications
  - Current regulatory expectations
  - Development, submission and implementation of Control Strategy for APIs
    - Role of assessor and inspector
  - Control strategy and recent ICH guidelines
    - IWG documents and IVH Q11
  - Starting materials – Scientific and regulatory consideration – GSK perspective

  Moheb Nasr, GSK

- **11:05 - 12:00 h**
  The importance of Quality Culture for the API Industry
  - What is quality culture?
  - What role does quality culture play in our industry?
  - Can quality culture be measured and if so what are the benefits?
  - Is/should quality culture important to the authorities?

  Anthony Storey, Pfizer

Lunch Break

- **13:30 - 14:20 h**
  Requirements of the API industry to allow the QP to perform their role/obligations
  - What are the legal requirements of QPs with regards to APIs
  - What do QPs expect from API suppliers/industry to support QPs to perform their legal obligations
  - What is changing in the QP role with regard to API quality oversight/requirements

  Veronique Davoust, EFPIA

- **14:20 - 15:10 h**
  Global inspection cooperation
  - An obligation of active substance manufacturer to ensure relevant quality of starting materials,
  - Intermediates resp. (purchased from third parties) for manufacturing active substances
  - Regulatory requirements
  - Starting raw materials definition
  - Requirements on GMP certificates

  Anne Hayes, IMB

Coffee Break

- **15:40 - 16:30 h**
  Challenges of implementing and assuring of a Good Distribution Practices System
  - Expectations and requirements from Regulators
  - Guidelines, Regulations and Guidance documents
  - Current activities of industry associations
  - GDP Quality Management System
  - Challenges of Supply Chain qualification

  Frithjof Holtz, Merck

- **16:30 - 17:20 h**
  Quality by Design: impact on inspections
  Vibhakar Shah, US FDA

Panel Discussion

Joint GMP and Regulatory Affairs Day

08:30 - 09:45 h
Parallel Sessions, Part A

- **Session 1:**
  ICH Q3D EWG Metal Impurities Update: Driving change to protect the patient and set consistent expectations for test requirements and regulatory filings
  - Building Consensus: Current status of Step 2 document
    - Alignment with ICH Q9 quality risk management principles
    - Process for safety assessments
    - Control strategy considerations and challenges
    - Expected regulatory filing requirements
  - Practical examples of how the guideline can be applied
  - Description of mechanisms to stay informed, influence the standard and its application

  Melissa Figgins, Sandoz

- **Session 2:**
  Cleaning Validation
  - Acceptance Criteria for Cleaning Validation - overview on the status of new guidances
  - Impact on API industry with some examples
  - APIC view
  - APIC guidance recommendations
  - Discussion Forum

  Tom Buggy, DSM Sinochem Pharmaceuticals

- **Session 3:**
  A single risk-based quality management system for small and large molecules
  - Differences in technologies
    - Dedicated versus multiproduct
    - Disposable technologies
    - Control of the environment
    - Material selection
    - Equipment selection
  - Quality System considerations, as per ICH Q7, chapter 19
    - General e.g. Technology transfer, risk assessment
    - Quality measures incl deviation management
    - Equipment and Facilities
    - Control of Raw materials
    - Production
    - Validation
    - Changes
    - Laboratory Controls
    - Documentation

  Fred Ward, Janssen Pharmaceutica

Coffee Break

10:15 - 11:30 h
Parallel Sessions, Part B

- **Session 4:**
  Measuring and Communicating a CMO's Quality Culture
  - Fundamentals of a Quality Culture
  - What are the Key indicators
  - How to measure the Key indicators
  - How to communicate them to the contractors

  Guy Villax, Hovione

- **Session 5:**
  OTCs in America, the Forgotten Drugs or a New Focus for the FDA?
  - APIs in OTC not covered under GDUFA, or are they covered by association?
  - US OTC inspections have uncovered major problems
  - FDA demands for greater supply chain security mean tighter control by final OTC manufacturers on API suppliers
  - Impact on OTC APIs due to Joint Agreement on Inspections between EMA and FDA

  Robert A. Dollinger, Novacyl

- **Session 6:**
  Current regulatory hurdles and opportunities – APIC's experiences
  - Do we have a workable definition of a "starting material"?
  - How much progress was made on EU centralised review of ASMFs?
  - Current experience in emerging markets
  - Current practical experiences with the CEP procedure

  Hilde Vanneste, Janssen Pharmaceutica
  Marieke van Dalen, MSD

Lunch Break

Joint GMP and Regulatory Affairs Day

- **13:05 - 13:55 h**
  The State of Play of Implementation of EU Directive 2011/62 on Falsified Medicines: API aspects
  - Short overview of the relevant API articles in the Directive
  - Delegated Acts and their status
  - Implementation Measures and their status
  - Other drafted and to be drafted related guidelines and other related documents
  - Timing
  - The issue of APIs within imported final medicinal products
  - What can be expected? / How will stakeholders and countries cope with the FMD?
  - What can we expect in terms of European API inspections outside the EU
  - What will be the role of EMA (short term and longer term)?
  - The written confirmation for APIs exported to the EU
  - Consequences for drug product manufacturers within the EU

  David Cockburn, EMA, UK (invited)

- **13:55 - 14:40 h**
  ICH Q11 – An Industry View
  - Scope of the guideline & main objectives
  - Manufacturing Process Development
    - Enhanced approach versus traditional
    - Design space
  - Manufacturing description
  - Starting materials
    - Principles on how to define them
  - Control strategy
    - Importance of it
    - Information expected
  - Process validation
  - Life Cycle Management
  - Which information is expected to be in the CTD/ industry constraints
  - Value of ICH Q11 – What does is not do
  - What are the benefits for industry to apply QbD

  Luc Janssens, Janssen Pharmaceutica

Coffee Break

- **15:10 - 16:00 h**
  Recent API-related Developments at FDA's Office of Generic Drugs: GDUFA & Question-Based Review
  - Status of GDUFA implementation at FDA
  - Details on the extension of FDA's work force
  - FDA's plan for reaching the GDUFA Goals by 2017, including geographic parity of global API inspections
  - Fees and how they are being calculated
  - Question-Based Review: What is it and how does it work for APIs?
  - API-related examples of QBR vs. OGD's approach in the past
  - Self-Identification and GDUFA fees of API facilities
  - The new completeness assessment of DMFs
  - Question-based Review (QbR) system for DMFs

  Aloka Srinivasan, Parexel

- **16:00 - 16:50 h**
  Continuous improvement: is it workable for dedicated API industry?
  - ICH Q11 expectations
  - Process improvements in dedicated API industry
  - Relationships with customers (the applicants)
  - Multi-customer situations
  - Regulatory strategies and timing

  Marieke van Dalen, MSD

- **16:50 - 17:40 h**
  New regulatory requirements in China
  - Overview of the most important changes (Regulatory and GMP Compliance) at introducing the new Regulatory and GMP in China
  - Impact to Chinese API manufacturers and impact to API intermediates manufactures
  - Mandatory SFDA inspection – risk based planning approach?
  - Roll out strategy and follow up strategy of SFDA
  - International pre-approval inspections for imported products (also API?)
  - Establishment of a DMF System and its impact if filing will be required for all components in a drug product submission
  - SFDA position versus the EU directive on falsified medicines and GMP statement on compliance to EU GMP requirements when importing APIs into EU
  - SFDA position on "acceptability on mutual recognition"

  Qing Shen, Shanghai FDA

Panel Discussion

Regulatory Affairs Conference

Objectives
After the several Regulatory topics presented during the second conference day, the RA conference will highlight the status of the Variations Regulation 2008/1234. First experiences with this new regulation and future developments will be shared with the audience. The following presentations will address workability aspects of continuous improvement for the dedicated API industry and the relevance of emerging markets for the API business. Updates on EMA's Quality Working Party activities as well as on EDQM's latest initiatives will round off the Regulatory Affairs Conference programme.

- **08:30 - 09.15 h**
  Status and lessons learned of variations regulation EC 2008/1234 implementation
  - An update on the status of the broadening the scope to include national procedures
  - Current experience with update variation regulation: EC point of view
  - Further plans of the EC for optimisation, evaluation, review and further update
  - Further plans on more flexible variation regulation for biologicals

  Peter Bachmann, CMDh Chair and BfArM, Germany

Regulatory Affairs Conference

- **09:15 - 10:00 h**
  Global pharmaceutical leader approach regarding the Regulatory environment of APIs
  - Global economic environment, Worldwide pressure on healthcare cost, Is it an option for pharmaceutical industry?
    - Developing the environmental aspect
  - Challenges driven by Regulatory environment of APIs, what are the risk for Pharmaceutical Industry?
    - Developing the main challenging for our Industry, (shortage, economic, organisation of the supply chain)
  - What is the risk associated for the patients?
  - After mitigation of the risk, what are the management options for Pharmaceutical Industry?

  Georges France, Novartis

Coffee Break

- **10:30 - 11:15 h**
  Update from the European Medicines Agency – Quality Working Party (QWP) regarding APIs
  - Different topics depending on the latest regulatory developments

  Jean-Louis Robert, Chairman of the EMA QWP, UK

- **11:15 - 12:00 h**
  Registration requirements for APIs in Emerging Countries
  - Regulatory requirements for post approval changes (e.g. change in API supplier)
  - Need, benefit and content expectations of site master file
  - What are CMC requirements needed from API manufacturer to keep product of marketing authorization holder registered on the market (renewal)?
  - What practice/system is used at the Health authorities to guarantee provided data are kept confidential?
  - How should industry work with different requirements from all different countries?

  Jan Smeets, DSM Sinochem Pharmaceuticals

- **12:00 - 12:45 h**
  EDQM – new developments
  - Update on European Pharmacopoeia
    - Monographs and general texts
    - Pharmacopoeial harmonization
  - Update on Anti-counterfeiting activities and eTACT service
  - Update on the Certification procedure
    - API Starting Materials evaluation experience; ICH Q11
    - Update on policies for evaluation of CEP applications
    - Update on centralized management of ASMF and new guideline on ASMF
    - EDQM inspections

  Hélène Bruguera, EDQM

Final Discussion / Closing Remarks

Speakers


Dr Peter Bachmann
CMDh Chair and BfArM, Germany


Hélène Bruguera
EDQM France


Tom Buggy
DSM Sinochem Pharmaceuticals Netherlands B.V., The Netherlands


David Cockburn
EMA, UK


Marieke van Dalen
MSD, The Netherlands


Veronique Davoust
EFPIA, Belgium


Robert A. Dollinger
Novacyl, USA


Melissa Figgins,
Sandoz, USA


Georges France
Novartis, Switzerland


Anne Hayes
IMB, Ireland


Frithjof Holtz
Merck, Germany


Luc Janssens
Janssen Pharmaceutica, Belgium


Moheb Nasr
GSK, USA


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Janssen Pharmaceutica, Ireland


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EMA QWP, UK


Qing Shen
Shanghai FDA, China


Vibhakar Shah,
Office of Compliance, CDER, US FDA


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Aloka Srinivasan
Parexel International, USA


Anthony Storey
Pfizer, UK


Hilde Vanneste
Janssen Pharmaceutica, Belgium


Guy Villax
Hovione, Portugal

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

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, 6 November 2012, 19.00 – 20.00 h or
Wednesday, 7 Nov 2012, 9.00 - 10.00 h
Regulatory Affairs Part:
Thursday, 8 November 2012, 8.00 - 8.30 h

Conference Date
Wednesday, 7 November 2012, 10.00 – 18.00 h
Thursday, 8 November 2012, 8.30 – 18.00 h
Friday, 9 November 2012, 8.30 – 13.00 h

Venue
Corinthia Grand Hotel Royal
Erzébet krt. 43-49
1073 Budapest, Hungary
Phone +36 (0) 1 479 4000
Fax: +36 (0) 1 479 4333

Fees
Book the GMP Part (7-8 November) or the Regulatory Affairs Part (8-9 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.
*per delegate + VAT

Discounts
APIC Members 10 %, ECA Members 5%, Inspectorates 25 %.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "Concept Heidelberg 6-9 Nov" to receive the specially negotiated rate (single room € 120,- per night, incl. breakfast, plus 18 % VAT) for the duration of your stay. Reservation should be made directly with the hotel not later than 23 October 2012. 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

15th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients
7 - 9 November 2012, Budapest, Hungary
I want to take part in

- ☐ **GMP Part** (7-8 November 2012)
- ☐ **Regulatory Affairs Part** (8-9 November 2012)
- ☐ **All three conference days** (7-9 November 2012)

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

First choice	Second choice	(in case your first choice is fully booked)
		Parallel Sessions I
☐	☐	Session 1: ICH Q3D EWG Metal Impurities Update
☐	☐	Session 2: Cleaning Validation
☐	☐	Session 3: A single risk-based quality management system for small and large molecules
		Parallel Sessions II
☐	☐	Session 4: Measuring and Communicating a CMO's Quality culture
☐	☐	Session 5: OTCs in America, the Forgotten Drugs or a New Focus for the FDA?
☐	☐	Session 6: Current regulatory hurdles and opportunities – APIC's experiences

☐ 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

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General Terms of Business
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:
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- until 2 weeks prior to the conference 10 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

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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. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!
(As of January 2012)