APIC Active Pharmaceutical Ingredients Committee a sector group of cefic

Europe's leading API Conference

13th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

27 - 29 October 2010, Barcelona, Spain

GMP Conference

27-28 October 2010

Regulatory Affairs Conference

28-29 October 2010

Authority Speakers:

Hélène Bruguera
EDQM, France

Olivier Gross
EMA, United Kingdom

Yoshikazu Hayashi
EMA, United Kingdom

Francois-Xavier Léry
EDQM, France

Moheb Nasr
FDA, USA

Sabine Kopp
WHO, Switzerland

Diana van Riet-Nales
EMA QWP, United Kingdom

Industry Speakers:

Lynne Byers
Rx-360

Eileen Counihan
Merck Sharp & Dohme Ltd., Ireland

Jens Donath
Lonza, Switzerland

Jean-Denis Mallet
International Committee Red Cross, Switzerland

Joachim Ermer
Sanofi Aventis, Germany

Oliver Grosche
Novartis, Switzerland

Georges France
Pfizer Animal Health, Belgium

Benny Goossens
Janssen Pharmaceutica, Belgium

Filipe Neves
Hovione, Portugal

Mary Oates
Pfizer, USA

Luisa Paulo
Hovione, Portugal

Anne Mieke Reijnders
eCTD Consultancy, The Netherlands

Anthony Storey
Pfizer, United Kingdom

Christian Tillmanns
meyer//meisterernst, Germany

Francois Vandeweyer
Janssen Pharmaceutica, Belgium

Hilde Vanneste
Janssen Pharmaceutica, Belgium

Steering Committee

We would like to express our sincere gratitude to the members of the steering committee for developing the conference:

Gerhard Becker,
CONCEPT Heidelberg, Germany

Rainer Fendt,
BASF, Germany

Pieter van der Hoeven,
CEFIC, Belgium

Henri Leblanc,
Rhodia, France

Matt Moran,
PharmaChemical, Ireland

Chris Oldenhof,
DSM Anti-Infectives, The Netherlands

Luisa Paulo,
Hovione, Portugal

Boris Pimentel,
DSM Nutritional Products, Switzerland

Stefan Rosenberger,
Lonza, Switzerland

Oliver Schmidt,
CONCEPT Heidelberg, Germany

Anthony Storey,
Pfizer, UK

Hana Tomkova,
Zentiva, Czech Republic

François Vandeweyer,
Janssen Pharmaceutica, Belgium

Hilde Vanneste,
Janssen Pharmaceutica, Belgium

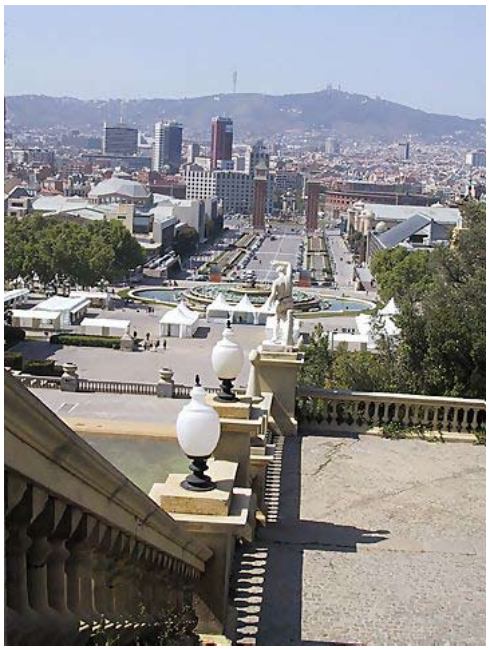
The Venue

The new Meliá Barcelona is located in the city's financial district, next to an exclusive shopping centre. It is 20 minutes from the city's international airport, 10 minutes from the exhibition centre and 5 minutes from the Sants railway station and high speed train. It also has excellent access to the most important highways providing access to the city.

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 and Venice).

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



13th APIC/CEFIC European Conference on

Active Pharmaceutical Ingredients

Objective

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, European Commission, EMA, EDQM, WHO, USP, National Authorities and from Industry will discuss the latest developments in the field of GMP and Regulatory Compliance.

API manufacturers as well as manufacturing authorisation holders are operating in a complex regulatory framework and they are facing global challenges regarding GMP and regulatory compliance. New approaches for ensuring compliance in a global context are being developed and implemented. For all stakeholders it will be of paramount importance to keep track of these developments and to anticipate the outcomes. As numerous professionals have found out during the past twelve years, in order to achieve these goals attending the APIC/CEFIC Conference on Active Pharmaceutical Ingredients is the best and fastest avenue.

Globalisation of the API business is now also increasingly leading to initiatives focusing on globalisation of regulatory frameworks and programmes. This is a very difficult process but more and more serious steps are being taken on the long and winding road towards such goals.

The APIC/CEFIC Conference is the leading international forum for discussions on all these important new developments. In addition, the conference will inform attendants also in detail about the latest and to be expected regulatory developments through presentations by representatives from major authorities. Moreover, six parallel sessions will provide the opportunity for an in-depth discussion on specific GMP and Regulatory Affairs topics.

Chairs

Matt Moran,
PharmaChemical Ireland

Chris Oldenhof,
DSM Anti-Infectives, The Netherlands

Anthony Storey,
Pfizer, UK

Hilde Vanneste,
Janssen Pharmaceutica, Belgium

GMP Conference

Objectives
The GMP Conference provides updates from amongst others the European and US Authorities on recent initiatives, activities as well as expectations and interpretations related to GMP compliance of API manufacturing. In addition an update on the activities connected with the new Joint International API Inspections Pilot Program will be presented.

Hear from the decision makers and opinion leaders from the authorities and industry the current activities in connection with the increasing demand of auditing and inspection of API manufacturing sites. Moreover, the interpretation and implementation of ICH Q9, Q10 and Q11 will be a key topic.

The specific GMP and Regulatory Affairs topics to be discussed in the Parallel Sessions will relate to Lean Labs in the API industry, APIC's Third Party Audit Scheme, Quality by Design (QbD) for analytical methods, QbD and Variations, Regulatory issues concerning APIs for OTC products and how to prepare API relevant information for the eCTD.

- **EMA and FDA joint inspections of API manufacturers – update**
  - Status of the joint API inspection program
  - Outcomes of the inspections
  - Exchange of inspection reports
  - EUDRA GMP Database
  - Views on the future of global coverage of API inspections

- **Current activities by Rx-360 regarding APIs**
  - Rx-360 and its role in assuring patient safety by enhancing supply chain integrity
  - Sharing of supplier audits within the scheme
  - Macro environment monitoring and information sharing

- **Focusing on fraud during GMP audits**
  - How to detect GMP deficiencies and fraud
  - Differences between audits in Europe and abroad
    - Cultural differences in Asia – How to inspect/audit outside of EU
    - Examples from audit experiences (API facilities)

- **Supplier management throughout the product lifecycle**
  - Current environment for the Industry
  - An approach to Supplier Management
  - Response by APIC to address the current environment
    - Supplier Management throughout the life cycle
    - Quality Agreement
    - Audit Programme

- **Continuous processing – challenges to the API industry**
  - Background to continuous processing, definitions and interpretation
  - Development from laboratory to commercial scale
  - Process validation considerations
  - Use of PAT
  - Green aspect of continuous manufacturing
  - Understanding the business case for continuous and way forward

- **How to implement Q11, Quality by Design and PAT**
  - ICH Q11 guideline status
  - ICH Q11 goals
  - API process development under QbD
    - Fundamentals
    - Risk assessment
    - Design Space
    - Control Strategy

- **FDA's Pharmaceutical Quality Initiatives – Progress and Challenges**
  - FDA Guidelines
  - ICH Guidelines
  - Status of implementation
  - Remaining challenges
  - Guidance for Industry: CMC Postapproval Manufacturing Changes Reportable in Annual Reports

- **Implementation of Q9, Q10, Q11**
  - How do they work together in practice?
  - What does a company need to do in order to be in compliance with all 3 guidances?
  - How will the authorities assess that a company is in compliance with all 3 guidances?
  - What are the advantages to industry of applying this approach?
  - What level of regulatory relief would industry expect from the application of these guidelines?

Joint GMP and Regulatory Affairs Day

Regulatory Affairs Conference

Parallel Sessions, Part A

Session 1:

- **Lean labs in API industry**
  - Case Study: Lean QC
    - Strategy development for a QC organisation
    - Lean tools in a QC environment (5S, Kaizen, Internal Audits)
    - KPI for a globally cooperating QC
    - Challenges in implementing new concepts

Session 2:

- **The role of Third Party Audits in global supply environment**
  - What are the advantages and disadvantages for industry using 3rd Party Audits?
  - What role can they play in the global situation of API supply and QP declaration requirement for APIs?
  - What is needed for a compliant Third Party Audit Scheme?
  - What are the key elements of such an effective and efficient scheme?

Session 3:

- **How to prepare API-related relevant Information for the eCTD**
  - How to author documents to build and maintain electronic ASMFs efficiently?
  - Pros and Cons of eCTD, NEES, Paper, considering global market supply?
  - How to create electronic ASMFs for eCTD and NEES (Non-eCTD electronic submission) formats?
  - A practical example: managing ASMFs (applicants and restricted part) by API holder vs managing eCTD (applicants part only) by Marketing Authorisation Holder

Parallel Sessions, Part B

Session 4:

- **How to deal with variations in a Quality by Design Environment**
  - Quality by Design
    - Motivation and goals
    - Fundamentals
  - Quality Changes
    - Types of changes
    - Types of variations
  - Handling variations through QbD
    - Design space
    - Control of raw materials
    - Control of final product
    - Manufacture

Session 5:

- **Legal aspects of the API sections of the EU Directive on Falsified Medicines**
  - Background for Regulatory Measures
  - Status of Legislative Procedure
  - Provisions on API
  - Impact on the Industry

Session 6:

- **Quality by Design for analytical methods**
  - Why QbD for analytical methods?
  - Risk analysis for analytical methods
  - Conventional approach versus QbD approach
  - Analytical Target profile concept
  - Method changes in the light of QbD
  - Impact on ICH Q2
  - Exercise: For API Quality Attributes such as assay of active and genotoxic impurity, the participants will by interactive discussion
    - Establish the Analytical Target Profile (ATP)
    - Select potential methods conforming to the ATP
    - Identify relevant method performance parameters and define validation acceptance criteria

Objectives
In the RA conference the new EU Directive on Falsified Medicines will be discussed. Moreover, the WHO will present an update of various current regulatory developments in the global context. EDQM will explain the latest developments regarding the CEP procedure and OMCL activities and another major topic will be regulatory requirements with regard to APIs in Japan. In addition an update on current and future USP activities on APIs will be presented.

- **Update from the EMA/QWP on API matters**

- **WHO current developments – what's new in the world?**
  - News from the global normative regulatory guidelines, including on stability
  - Updates on The International Pharmacopoeia
  - WHO anti-counterfeiting activities
  - Current developments in the prequalification procedures

- **Regulatory requirements with regard to APIs in Japan**
  - Marketing approval system in the Pharmaceutical Affairs Law in Japan
  - Master file system (e.g. Contents required for the master file registration)
  - GMP compliance inspection by PMDA (Site inspection/ Desk top inspection)
  - Points to remember when you receive GMP compliance inspection

- **How to do Document – a Guidance for Implementation of ICH Q7**
  - What to do to implement ICH Q7 GMP for API manufacturing
    - API starting material
    - Quality Unit
    - Product Quality Review
    - Production Operations
    - Certificates of Analysis
    - Change Control

- **ICH Guidances and Implementation in non-ICH Regions: How the rest of the world handles it**
  - The role of ICH in global harmonisation of GMP and regulatory requirements within the API Industry
  - The advantages of adopting ICH requirements
  - Which markets/regions does ICH apply and regions or markets that have requirements different to those of ICH and their implications
  - Inconsistencies within the ICH regions and the consequences of this activities
  - What should the authorities and industry do to resolve these inconsistencies to ensure all markets move to ICH requirements

- **Hurdles and opportunities for API industry to get safe molecules to the patient while allowing improvements and changes**
  - Does the updated Variations Regulation 1234/2008 provide a simpler, clearer and more flexible legal framework, while guaranteeing the same level of public and animal health protection?
  - How harmonised are EU guidelines over all EU countries?
  - Regulatory dossier and compliance challenges for companies producing and selling world wide

- **Update on the OMCL API fingerprinting programme by EDQM**
  - Triggers for the programme
  - Role of OMCL Network
  - How EDQM deals with data confidentiality
  - Type of analytical methods needed
  - End-users: Industry/Authorities, Europe and beyond
  - Looking for synergies

- **Latest developments of EDQM activities with regard to CEPs and harmonization of Pharmacopoeias**
  - Update on EDQM's worldwide API inspection programme and its results
  - The new System for CEP Revisions / Renewals and how it relates to the revised Variations Regulation
  - Update on harmonisation with USP and Japanese Pharmacopoeia

Speakers

Hélène Bruguera
European Directorate for the Quality of Medicines (EDQM & Health Care), France. Deputy Head of Division and in charge of the management of revisions of CEPs

Francois-Xavier Léry
European Directorate for the Quality of Medicines (EDQM & Health Care), France. Responsible for anti-counterfeiting projects i.e. Track & Trace of mass-serialised pharmaceutical items and API fingerprinting.

Moheb Nasr
Director of the Office of New Drug Quality Assessment (ONDQA) in FDA's Center for Drug Evaluation and Research.

Sabine Kopp
Secretary of the WHO Expert Committee on Specifications for Pharmaceutical Preparations and Programme Manager of the WHO Medicines Quality Assurance and Anti-Counterfeiting Programmes.

Lynne Byers
Vice Chair of Rx-360.

Eileen Counihan
Merck Sharp & Dohme Ltd, Ireland. Director Commercialization and EMA Compliance

Jens Donath
Head of LCMC QC / Visp, responsible for the analytical support of the production facilities for small molecules, synthetic peptides and armed drug conjugates and the global QC harmonisation efforts within the business unit LCMC.

Joachim Ermer
Head of Quality Control Chemistry at Sanofi-Aventis Deutschland GmbH in Frankfurt, Germany.

Georges France
Head of Pfizer Quality Strategy and member of the ICH IWG

Benny Goossens
Janssens Pharmaceutica (part of Johnson & Johnson)

Oliver Grosche
Analytical Network Leader in Technical Development at Novartis Pharma AG, Basel, Switzerland.

Olivier Gross
Scientific administrator Manufacture and Quality Compliance at the inspection sector at EMA, London.

Yoshikazu Hayashi
MHLW / PMDA Liaison Official at the EMA

Jean-Denis Mallet
GMP Auditor within the International Committee Red Cross Pharmaceutics, Switzerland. Previously Head of the Pharmaceutical Inspection Department at the French Health Products Regulatory Agency.

Filipe Neves
Assistant Engineer in the R&D Particle Design Discipline at Hovione FarmaCiencia SA, Loures, Portugal.

Mary Oates
Vice President, Global Quality Operations at Pfizer USA and responsible for all aspects of Quality Operations for both clinical and commercial manufacturing.

Luisa Paulo
Compliance Director at Hovione and Vice Chair of APIC's Good Manufacturing Practices & Quality Assurance Working Group.

Anne Mieke Reijnders
eCTD Consultancy, The Netherlands

Diana van Riet-Nales
Deputy Head of the section Chemical Pharmaceutical Assessment (CFB) at the Dutch National Institute for Public Health and the Environment (RIVM) and Vice-Chair of the EMA / CHMP's Quality Working Party

Anthony Storey
API QA manager at Pfizer, Sandwich, United Kingdom and currently vice president of APIC.

Christian Tillmanns
Lawyer specialized in pharmaceutical and medical devices law in the law firm meyer// meisterernst, Munich, Germany.

Francois Vandeweyer
Director Global Compliance EMA/AP for Johnson & Johnson

Hilde Vanneste
Regulatory affairs and compliance manager, for active pharmaceutical ingredients at Janssen Pharmaceutica, Belgium. Member of the APIC executive committee and task force leader for the update of the Variations Regulation within APIC.

About CEFIC

CEFIC, the European Chemical Industry Council, is the Brussels-based organisation representing national chemical federations and chemical companies of Europe. All in all, CEFIC represents, directly or indirectly, more than 29,000 large, medium and small chemical companies in Europe, which employ about 1.7 million people and account for nearly one third of world chemical production.

About APIC

APIC is one of CEFIC's Sector Groups, comprising producers of active pharmaceutical ingredients (APIs) and intermediates in Europe. For this reason APIC considers itself to be a very important stakeholder in new EU Regulations and Guidelines related to APIs and intermediates. Our 64 members are located all over Europe and include three national associations: AFAQUIM (Spain), PHARMACHEMICAL IRELAND (Ireland) and SICOS (France).
APIC's key objectives are:

- To promote the use of compliant APIs in medicinal products to ensure patient safety
- To represent the interests of pharmaceutical and chemical companies producing APIs and intermediates in Europe by being recognized experts who advance and influence the global GMP and Regulatory environment.

APIC is very active in communicating and monitoring developments of the active pharmaceutical ingredients industry as well as in defending the APIC views and positions on proposed legislation, regulations and guidelines.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Germany, Austria and Switzerland. This year, more than 240 events will be organised by CONCEPT HEIDELBERG.

Conference Exhibition

Would you also like to present an exhibition stand?

Please contact Ms Marion Grimm at phone + 49-6221/ 84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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
www.concept-heidelberg.de

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

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, 26 October 2010, 19.00 – 20.00 h or
Wednesday, 27 October 2010, 09.00 h - 10.00 h
Regulatory Affairs Part: Thursday, 28 October 2010, 8.00 - 8.30 h

Conference
Wednesday, 27 October 2010, 10.00 h – 18.00 h
Thursday, 28 October 2010, 08.30 h – 18.15 h
Friday, 29 October 2010, 09.00 h – 14.00 h

Venue
Hotel MELIÃ BARCELONA
C/ Avenida Sarriá, 50
08029 Barcelona
Spain
Phone: +34 93 410 60 60
Fax: +34 93 410 77 44

Fees
Book the GMP Part (27-28 October) or the Regulatory Affairs Part (28-29 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%, Inspectorates 25%, ECA Members 5%. **Please note that discounts cannot be combined!**

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" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 26 September 2010. 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.

If the bill-to-address deviates from the specification to the right, please fill out here:

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13th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients
27 - 29 October 2010, Barcelona, Spain
I want to take part in

- ☐ **GMP Part** (27-28 October 2010)
- ☐ **Regulatory Affairs Part** (28-29 October 2010)
- ☐ **All three conference days** (27-29 October 2010)

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: Lean Labs in API Industry
☐	☐	Session 2: The role of Third Party Audits in global supply environment
☐	☐	Session 3: How to prepare API-related relevant information for the eCTD
		Parallel Sessions II
☐	☐	Session 4: How to deal with Variations in a Quality by Design Environment
☐	☐	Session 5: Legal aspects of the API sections of the EU Directive on Falsified Medicines
☐	☐	Session 6: Quality by Design for Analytical Methods

☐ Mr ☐ Ms Title _____

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

First name, surname

Company ☐ APIC Member ☐ Inspectorate

Department

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E-mail (please fill in)

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:
Cancellation
- 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.

CONCEPT reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**