APIC Active Pharmaceutical Ingredients Committee a sector group of cefic

Europe's leading API Conference

Authority Speakers:

Christine Moore
FDA, USA

Rosimeire Pereira Alves da Cruz
ANVISA, Brazil

Isabella Marta
AIFA, Italy

Lionel Viornéry
AFSSAPS, France

Hélène Bruguera
EDQM, France

Stefan Führing
European Commission, Belgium

Diana van Riet-Nales
National Institute for Public Health and Environment, The Netherlands; EMA Quality Working Party

Christa Wirthumer-Hoche
AGES PharmMed, Austria

Industry Speakers include:

Gretchen Allison
Pfizer, United Kingdom

Tom Buggy
DSM Sinochem, The Netherlands

Eileen Counihan
Merck Sharp & Dohme Ltd., Ireland

Marieke van Dalen
Merck Sharp & Dohme BV, The Netherlands

André Littek
Bayer HealthCare, Germany

Julie Maréchal-Jamil
European Generic Medicines Association, Belgium

Mary Oates
Pfizer, USA

Chris Oldenhof
DSM Sinochem, The Netherlands

Bernd Schade
Germany

Jan Smeets
DSM Sinochem, The Netherlands

Claudia Stampfli
Lonza, Switzerland

Hilde Vanneste
Janssen Pharmaceutica, Belgium

Guy Villax
Hovione, Portugal

Brian Withers
Abbott, United Kingdom

NEW: Additional Pre-Conference Session on ICH Q11 on 15 November!

14th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

16 – 18 November 2011, Munich, Germany

GMP Conference

16 – 17 November 2011

Regulatory Affairs Conference

17 – 18 November 2011

Media Partner:

"The Gold Sheet" SECURING PHARMA IPQ

14th APIC/CEFIC European Conference on

Active Pharmaceutical Ingredients

Objective

Already since 1998 the APIC/CEFIC Conference on Active Pharmaceutical Ingredients is Europe's leading event. Its programme always constitutes an optimal balance between contributions from the Health Authorities and from the Industry. This year we expect to welcome speakers from US/FDA, European Commission, EMA, Heads of (Europe's) Medicines Agencies, EDQM and National Authorities as well as from Industry and Industry Associations. All major new developments in the field of GMP and Regulatory Compliance will be discussed.

API manufacturers as well as manufacturing authorisation holders are operating in an environment consisting of different, complex regulatory frameworks that are, today more than ever before, subject to change. As a result, industry is today once more facing many new, global challenges regarding GMP and regulatory compliance.

The recently issued EMA draft template for the Qualified Person's API GMP declaration and verification of its supply chain opens with the statement:
"The quality of medicinal products depends to a large degree on the quality of the active substances used to formulate them".
This underlines that one of the main themes of this moment is the globalisation and international cooperation regarding oversight over the API supply chain. Prominent health authorities as well as the industry itself have drastically increased their attention for ensuring the safety of APIs and the involved supply chains. A major legislative development is the new EU Directive on Falsified Medicines, amending Directive 2001/83, that was adopted by the European Parliament on 16 February 2011. In parallel similar legislative initiatives are in advanced stages in the US while also the Council of Europe's so-called MEDICRIME Legal Convention is available for signing by CoE member states but also by any non-CoE members.
Is the industry prepared for the impact of this soon to be upgraded regulatory environment in which compliance will, yet much more than before, be a decisive factor that determines success and failure in the pharmaceuticals business?

By attending this conference you will become optimally aware of where your company will need to focus on in order to cope with all the upcoming challenges.
Recent examples have clearly illustrated that the new legislative frameworks are even already casting their shadows forward. Compliance issues relating to APIs have started to hit pharmaceutical businesses quite hard and this is a trend that we can expect to continue.

The APIC/CEFIC Conference on Active Pharmaceutical Ingredients provides the best forum to obtain first hand information. Moreover, six parallel sessions will provide the opportunity for yet more in-depth discussions on specific GMP and Regulatory Affairs topics.

Chairs

Matt Moran,
PharmaChemical Ireland

Anthony Storey,
Pfizer, UK

Nessa Moyles,
PharmaChemical Ireland

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

Marieke van Dalen,
Merck Sharp & Dohme BV, The Netherlands

Rainer Fendt,
BASF, Germany

Pieter van der Hoeven,
CEFIC, Belgium

Matt Moran,
PharmaChemical, Ireland

Nessa Moyles,
PharmaChemical Ireland

Chris Oldenhof,
DSM Anti-Infectives, The Netherlands

Luisa Paulo,
Hovione, Portugal

Boris Pimentel,
DSM Nutritional Products, 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

GMP Conference

Objectives
The GMP Conference, of which the final part is a Joint GMP & RA session, provides updates from the European, US and National Authorities on recent initiatives, activities as well as expectations and interpretations related to GMP compliance of API manufacturing. In addition, industry speakers will present their best practices on compliance with the various existing and emerging aspect of API GMP.

As usual, FDA will clarify the latest developments regarding its quality initiatives and will present its enforcement strategies on APIs. Of course there will be much attention for the API aspects of the new EU Directive. In addition the FDA API process validation guidance will be discussed.

Worldwide API inspection experiences will be shared with the audience by AFSSAPS France.

Another key topic will be the risk-based oversight over contract manufacturing and other outsouced activities.
Other topics include initiatives to harmonise dossier assessment in the EU, the prevention of contamination in API manufacturing sites and the Italian requirements for import and registration of APIs.

Last but not least there will be an update on the progress of the crucial API guideline ICH Q11.

The specific GMP and Regulatory Affairs topics to be discussed in the Parallel Sessions will relate to best inspection practices to detect fraud, implementation of supplier qualification in API production, APIC's view on current regulatory issues, Rx-360, eCTDs and to EMA's draft guidance on impurities in antibiotic APIs.

Programme

- 10.10 - 11.05 h
  Inspection findings at API facilities: Outcomes and Trends
  Lionel Viornery, AFSSAPS

- 11.05 - 12.00 h
  API aspects of the draft EU Directive on Falsified Medicines
  - Outline of API aspects of the new amending Directive on Falsified Medicines
  - Relevant definitions
  - Implications for the EU's worldwide API inspection activities
  - Available enforcement tools, measures, sanctions in situations of API falsification

  Stefan Führing, European Commission

  Lunch Break

- 13.30 - 14.20 h
  Contamination prevention in multipurpose chemical API facilities/a risk based approach
  - Sources of contamination
  - Dedicated facilities
  - Multipurpose facilities and equipment
  - Risk based process proposal
    - Product types and level of protection
    - Contamination prevention for open product processing and handling
    - Contamination risk reduction
    - Responsibilities
  - Importance of contamination control on "other" sources

  Tom Buggy, DSM Sinochem

- 14.20 15.10 h
  Definition of the API Starting Material: A science-based approach
  - What is the total manufacturing process for producing a medicinal product?
  - How does the process relate to the quality and safety of the API?
  - The Big Blind Spot
  - Examples of non-science-based criteria
    Practical considerations
  - Theory vs. Real Life
  - The science-based approach

  Chris Oldenhof, DSM Sinochem

  Coffee Break

- 15.40 - 16.30 h
  FDA Guidance on Process Validation for APIs: an Industry perspective
  - Scope of FDA Process Validation Guide and 3 Stages of the Lifecycle
  - Definitions and References
  - Industry feedback on guide
  - API specific points
  - Main industry gaps with the guide

  Gretchen Allison, Pfizer

- 16.30 - 17.20 h
  Risk-based approach to quality oversight in contract manufacturing – outsourced activities
  - Why API contract manufacturing is being used by the industry today and attracting more attention by regulatory authorities
  - What systems are needed at contract giver and receiver to support effective contract manufacturing quality systems
  - The role risk management principles can play in supporting contract management from a resource and quality oversight perspective
  - The importance of monitoring contracts and building good working relationships between contract givers and acceptors

  Mary Oates, Pfizer

  Panel Discussion

Joint GMP and Regulatory Affairs Day

08.30 - 09.45 h **Parallel Sessions, Part A**

Session 1:

- **Best practices in GMP inspections to increase the detection of fraud**
  - Different focus for the inspection of
    - Starting materials
    - Supplier qualification, evaluation, surveillance
    - Yield
    - Material balance
    - Extended document checks

  Bernd Schade, Germany

Session 2:

- **How to implement supplier qualification in API Manufacturing**
  - Discussion on current scope (internal and external)
  - Current Challenges
    - Relevant issues in the Quality Agreement
    - Early collaboration with Supplier
    - Management of change
    - Appropriate specifications
    - Others
  - Maximising the value
    - Alignment of schedules
    - Suppliers knowledge

  Eileen Counihan, MSD

Session 3:

- **Present regulatory hurdles and opportunities – APIC's experiences**
  - Recent developments in the CEP procedures
  - eCTD: ASMF submissions for centralised procedures at EMA: a real live example
  - API starting materials
  - DMFs in Japan

  Marieke van Dalen, MSD, Hilde Vanneste, Janssen Pharmaceutica, Belgium

Coffee Break

10.15 - 11.30 h **Parallel Sessions, Part B**

Session 4:

- **An update on Rx-360**
  - Overview of the current organisation of Rx-360
  - An update on the Rx-360 audit pilot programme
  - Next actions of Rx-360 on rolling out the audit scheme as potential collaboration with third party audit schemes
  - Other Rx-360 initiatives to support supply chain integrity of APIs
  - The benefits of being an Rx-360 member

  André Littek, Bayer HealthCare

Session 5:

- **eCTD: How to Do - from the perspective of the API manufacturer**
  - Overview of the Regulatory Framework
  - Options and considerations for API manufacturers to handle eCTD requirements
    - Outsourcing solution
    - Inhouse software
    - Host system option
  - Preparation of eCTD ready documents

  Claudia Stampfli, Lonza

Session 6:

- **New EMA guidance on impurities related to antibiotics / products of fermentation**
  - Do we really need such a guideline?
  - If yes, scope of guideline:
    - only antibiotics or all substances manufactured by fermentation and semi-synthesis?
    - new and/or existing substances
  - Is it possible to classify this divers group of substances into only 3 sets of applicable thresholds?
  - Are proposed thresholds realistic?
  - Consequences for substances already many years on the market with a history of safe use
  - Consequences for existing Ph.Eur. monographs

  Jan Smeets, DSM Sinochem

- 13.05 - 13.55 h
  FDA's Pharmaceutical Quality Initiatives
  - The new QbD Pilot with the European Medicines Agency
  - ICH Q11
  - The impact of the new Process Validation Guide
  - Important aspects for API industry
  - Next steps (initiatives, guidelines)

  Christine Moore, FDA

- 13.55 - 14.40 h
  The Competitive Advantage of non-Compliance
  Guy Villax, Hovione

  Coffee Break

- 15.10 - 16.00 h
  Harmonised ASMF assessment - HMA initiative
  - EU numbering system of ASMF
  - Assessment of ASMF - Worksharing
  - Common IT platform for ASMF-ARs

  Christa Wirthumer-Hoche, AGES PharmMed

- 16.00 - 16.50 h
  Italian requirements for the import of APIs
  Isabella Marta, AIFA

- 16.50 17.40 h
  The new ICH Q11 Guidance on Development and Manufacture of Drug Substances
  Brian Withers, Abbott

Regulatory Affairs Conference

Objectives
After the several Regulatory topics presented during Day Two of the conference, the RA conference will highlight the current workplan of the EMA Quality Working Party and EDQM's update of its activities with regard to the CEP procedure, including its API inspection programme. In addition a special topic on the impact of patent expiry on regulatory assessments will be discussed. This is followed by an update on regulatory guidance on APIs for the Brazilian market. The Conference is rounded off by an evaluation of the new EU Variations Regulation.

■ 08.30 - 09.20 h
European Generic Medicines Pharmaceutical Industry's Experience with the new Variations Regulation
- Industry experience to date
  - Type IA
  - Type IB
  - Groupings
  - Worksharing
  - Fees
- Possible improvements
- Conclusions

Julie Maréchal-Jamil, EGA

■ 09.20 - 10.10 h
Current EDQM activities and developments
- Update on the European Pharmacopoeia
- Update on anti-counterfeiting activities: The Council of Europe's Medicrime Convention and EDQM's practical activities in the field
- What's happening in pharmacopoeial harmonisation?
- EDQM's international activities

Hélène Bruguera, EDQM

Coffee Break

■ 10.40 - 11. 30 h
Current trends on CEPs
- EDQM experience with API Starting Materials
- Update on policies for evaluation of CEP applications
- Update on EDQM inspections and international collaboration in this field

Hélène Bruguera, EDQM

■ 11.30 - 12.20 h
How patent expiry triggers inconsistency in API assessments – A case study
- Use of originator's API: does this simplify registration?
- Use of a CEP vs. use of an ASMF
- (in-)consistency between and within Has
- Effects on the originator's products

Marieke van Dalen, Merck Sharp & Dohme

■ 12.20 - 13.10 h
New regulatory guidance and regulation on APIs for the Brazilian market
- Brazilian legislation for APIs
- The Brazilian market on APIs
- International API inspection program
- Inspection status of API sites (statistics, major deficiencies observed, other remarks)

Rosimeire Pereira Alves da Cruz, ANVISA, Brazil

■ 13.10 - 14.00
Guidance on regulatory API starting materials and current workplan of the EMA Quality Working Party
Diana van Riet-Nales, National Institute for Public Health and Environment; EMA QWP

Panel Discussion, Closing Remarks

Speakers

Gretchen Allison
Pfizer, United Kingdom

Hélène Bruguera
European Directorate for the Quality of Medicines (EDQM & Health Care), France

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

Eileen Counihan
Merck Sharp & Dohme Ltd, Ireland

Rosimeire Pereira Alves da Cruz
ANVISA, Brazil

Marieke van Dalen
Merck Sharp & Dohme BV., The Netherlands

Stefan Führing
Unit pharmaceuticals, Health and Consumers Directorate-General, European Commission, Belgium

André Littek
Bayer HealthCare, Germany

Speakers

Julie Maréchal-Jamil
European Generic Medicines Association, Belgium

Isabella Marta
AIFA, Italy

Christine Moore
Deputy Director Science and Policy, Office of New Drug Quality Assessment (ONDQA), CDER, FDA, USA

Mary Oates
Pfizer, USA

Chris Oldenhof
DSM Sinochem Pharmaceuticals B.V., The Netherlands

Diana van Riet-Nales
National Institute for Public Health and Environment, The Netherlands; EMA QWP

Bernd Schade
Formerly Bayer Healthcare, Germany

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

Claudia Stampfli
Lonza Ltd, Switzerland, leader of the APIC task force „eCTD".

Hilde Vanneste
Janssen Pharmaceutica, Belgium

Guy Villax
Hovione, Portugal

Lionel Viornéry
AFSSAPS, France

Christa Wirthumer-Hoche
Deputy Head of AGES PharmMed, Austria

Brian Withers
Abbott, United Kingdom

The new ICH Q11 Guideline:
„How to comply with ICH Q 11"
a pre-Conference Session on 15 November 2011

This course is designed as a pre-Conference Session and ideally complements the subsequent 14th APIC/CEFIC Conference on Active Pharmaceutical Ingredients.

If you register both for the pre-Conference Session on ICH Q11 and the 14th APIC/CEFIC Conference you will benefit from a special rate of 690 € for the pre-Conference Session!

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 Munich and invite all participants and speakers to an entertaining evening outside the hotel followed by a dinner.

Lufthansa Official Airline

Special offer with Lufthansa – discounted travel for 14th APIC/CEFIC Conference attendees

Lufthansa German Airlines offers a comprehensive global route network linking München with major cities around the world. As the Official Airline to this event, Lufthansa offers special prices and conditions to all attendees.
To make your reservation, please click on the link you will receive with your registration confirmation and enter the access code **DEFZQ** in the „Access to Event Booking" area. 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.
Please note that you may have to enable pop-ups on this site – otherwise the booking platform window will not open. These promotional fares are also available via your IATA/ARC Travel Agent. Travel Agents can obtain ticketing instructions via eMail lufthansameetingsandevents.ber@dlh.de by quoting the access code as an event reference.

The Venue

Light makes life brighter and more attractive, therefore a unique light and music concept was implemented in the Leonardo Royal Hotel Munich. The right light at the right time to the right music – with this combination the »Leo90« lounge turns the Leonardo Royal Hotel into the »place-to-be«, the perfect location for relaxation or good conversations. Unique. Stylish. Modern. The four-star superior hotel welcomes you to its distinctive ambience. Come and experience for yourself a true symbiosis of modern architecture, tasteful interior and a harmonious colour concept. The conference area of 1,800 square metres, the 424 attractive rooms and suites, the restaurant, executive lounge, the Zino Cigar Lounge by Davidoff and the sauna and fitness area all speak volumes.

Only one step to tranquility, well-being and relaxation: The lounge terrace of the Leonardo Royal Hotel Munich offers a marvellous view of the garden surrounding the hotel – a view that promises »resort-feeling-in-the-city«. Also the wellness area with its stylish relaxation room, modern fitness equipment and two saunas makes it easy to forget the rush of everyday life. Just like the adjacent Olympic Park, Munich's central point for leisure sports. Whether jogging, Nordic walking, swimming or inline skating, the facilities at Olympia standard will satisfy even highest sporting aspirations.

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.

Media Partner

SECURING PHARMA

SecuringPharma.com is a free-to-access information service that covers the issues surrounding counterfeit medicines and supply chain security in the pharmaceutical industry. Our aim is to provide practical advice and market intelligence to help drugmakers keep up-to-date with developments in the field and define their own strategies to safeguard the supply chain, from raw materials right through to the patient.
www.securingpharma.com

"The Gold Sheet"

„The Gold Sheet" provides the most insightful analysis to help you comply with pharmaceutical manufacturing QA/QC requirements in the U.S. and internationally. http://thegoldsheet.elsevierbi.com.

IPQ

The International Pharmaceutical Quality Journal's (IPQ) monthly format keeps subscribers "Inside the Global Regulatory Dialogue"™ where the initiatives are being defined that will reshape the landscape. The IPQ is one of the most important Journals in the GMP and regulatory environment. www.ipqpubs.com.

Easy Registration

Reservation Form:
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Germany

Reservation Form:
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e-mail:
info@concept-heidelberg.de

Internet:
www.api-conference.org

Registration
Tuesday, 15 November 2011, 19.00 – 20.00 h
or Wednesday, 16 November 2011,
9.00 h - 10.00 h
Regulatory Affairs Part:
Thursday, 17 November 2011, 8.00 - 8.30 h

Conference
Wednesday, 16 November 2011,
10.00 h – 18.00 h
Thursday, 17 November 2011, 8.30 h – 18.00 h
Friday, 18 November 2011, 8.30 h – 14.00 h

Venue
Leonardo Royal Hotel Munich
Moosacher Straße 90
80809 Munich, Germany
Phone: +49 (0) 089 288 538 0
Fax: +49 (0) 089 288 538 100

Fees
Book the GMP Part (16-17 November) or the Regulatory Affairs Part (17-18 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.

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 16-18 Nov" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 4 October 2011. 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

14th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients
16-18 November 2011, Munich, Germany
I want to take part in

- ☐ **GMP Part** (16-17 November 2011)
- ☐ **Regulatory Affairs Part** (17-18 November 2011)
- ☐ **All three conference days** (16-18 November 2011)

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: Best practices in GMP inspections to increase the detection of fraud
☐	☐	Session 2: How to implement supplier qualification in API production – How to do
☐	☐	Session 3: Present regulatory hurdles and opportunities – APIC's experiences
		Parallel Sessions II
☐	☐	Session 4: Rx-360
☐	☐	Session 5: eCTD: How to do
☐	☐	Session 6: New EMA guidance on impurities related to antibiotics/products of fermentation

☐ **I also register for the pre-Conference Session „How to comply with ICH Q11" at the special rate of 690 € plus VAT**

☐ Mr ☐ Ms Title _____

First name, surname

Company ☐ APIC Member ☐ Inspectorate

Department

Important: Please indicate your company's VAT ID Number **P.O. Number if applicable**

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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)!**