

Europe's
leading
API Conference

Authority Speakers confirmed:

Moheb Nasr

*Director CDER/ONDQA
US/FDA*

Chris Cullen

Irish Medicines Board, Ireland

Diana van Riet-Nales

*National Institute for Public
Health and Environment,
The Netherlands*

Jean-Louis Robert

*EMA/QWP Chairman,
Luxemburg*

Nicolas Rossignol

*European Commission,
DG Enterprise & Industry,
Belgium*

Corinne Pouget

EDQM, France

Francois-Xavier Lery

EMA, UK

Zofia Ulz

*Main Pharmaceutical
Inspectorate, Poland*

Susanne Keitel

BfArM, Germany

Industry Speakers confirmed:

Tom Buggy

*DSM Anti-Infectives,
The Netherlands*

Malcolm Holmes

GlaxoSmithKline, UK

Hendrik de Jong

*Servier IRIS, France,
Chair of the European
Pharmacopoeia Commission*

Karl Metzger

Welding, Germany

Gerald Migliaccio

Pfizer, USA

Britta Rotte

Merckle, Germany

Jordi Ruiz-Combalia

Bioiberica, Spain

Kathleen Wessberg

Abbott, USA

Neil Wilkinson

AstraZeneca, UK

Hilde Vanneste

Janssen Pharmaceutica, Belgium

Vitalijs Skrivelis

Grindeks, Latvia

Dan Pilipauskas

Pfizer, USA

Yueping Sun

CHNMED, China



**10th APIC/CEFIC
European Conference on
Active
Pharmaceutical
Ingredients**

24 - 26 October 2007, Warsaw, Poland

GMP Conference

24 - 25 October 2007

**Regulatory Affairs
Conference**

25 - 26 October 2007

Exclusive Media Partner:

10th APIC/CEPIC European Conference on Active Pharmaceutical Ingredients

Conference Programme

The 10th APIC/CEPIC European Conference on Active Pharmaceutical Ingredients will take place in Warsaw, Poland, this year.

In a rapidly changing legislative environment API manufacturers as well as manufacturing authorisation holders are facing global challenges regarding GMP and regulatory compliance.

During last year's APIC Conference in Prague these issues provoked lively and extensive discussions which demonstrated the importance of this event for the API industry.

By attending the 10th APIC/CEPIC Conference on APIs you will get first hand information on the latest developments on GMP and Regulatory Affairs.

We have invited speakers from EU, FDA, EMEA, EDQM and national authorities who will present updates on their recent and upcoming activities.

A special feature of the joint day will be 8 highly interactive parallel sessions on specific GMP and Regulatory Affairs topics. Participants have the opportunity to choose between different topics.

The conference will allow enough time for networking with other colleagues to exchange information about best practices among industry representatives and to get into contact with high ranking officials from EU, FDA and inspectors.

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

Pieter van der Hoeven, CEPIC, Belgium

Henri Leblanc, Rhodia, France

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

Stephan Rosenberger, Lonza AG, Switzerland

Oliver Schmidt, CONCEPT Heidelberg, Germany

Anthony Storey, Pfizer, UK

Thomas Zwier, Pfizer, USA

GMP Conference

Objective

The API industry has to comply with the increased requirements of the revised European legislative framework together with the supporting guidelines. Auditing, inspections by authorities, certification procedures and the requirements of ICH Q7A are the key issues.

By attending the GMP Conference you will get updates from the European and US Authorities on their initiatives, activities, expectations and interpretations related to GMP compliance of API manufacturing.

Hear from the decision makers from the authorities and industry how to implement the new requirements in order to be in line with European and US legislation.

In the Parallel Sessions key topics will be discussed such as Third Party Auditing, Quality Agreements, implementation of ICH Q10, APIs for use in clinical trials, risk considerations in API manufacturing, the quality by design approach, aspects of good storage/good transportation practice and defining API starting materials.

Update on EMEA's activities related to API compliance

- Recent Guidance on API-related inspections
- Priority-setting & coordination of API-related inspections
- API Inspection Triggers: How does the guidance work in practice?
- Results of the evaluation of the API compliance situation as observed during recent dosage form manufacturers inspections
- Third Party Auditing: Update on what is acceptable practice and what isn't
- Harmonisation of API inspectional approaches / role of EMEA's GMP inspection Services Group
- Upcoming API-compliance related actions within EMEA's work plan
- EUDRA GMP Database & APIs
- Progress on the design of a follow-up procedure after CEP suspensions

Francois-Xavier Lery, EMEA, UK

FDA Quality Initiatives – an update

Moheb Nasr, FDA, CDER-ONDQA, USA

Implementation of GMP-compliant API manufacturing in Poland according to the European legislation

Zofia Ulz, Main Pharmaceutical Inspectorate, Poland

Inspections and APIs from Irish Medicines Board perspective

- The API industry in Ireland – a brief review
- IMB inspection experiences of API manufacturing
- Future developments in API manufacturing in Ireland from a regulator's perspective
 - API/drug product intermediate manufacturing
 - IMP manufacturing by API manufacturers
 - Comparison of GMP requirements for API manufacturers and drug product manufacturers

Chris Cullen, Irish Medicines Board, Ireland

Supplier assessments - a challenge we accepted. View from a Generic Company

- Ratiopharm group – a short overview
 - Supplier assessment
 - Who is responsible / involved?
 - Challenges – What does it mean?
 - Risk assessment – How to handle the challenge
 - Which tools do we use?
 - Paper assessment – Questionnaires, certificates, 3rd party reports
 - On-site assessments – audits, technical visits
 - Possible assessment results – qualified, not in compliance with...
 - Assessment frequencies – Does a dependency between assessment result and frequency exist?
 - How to distribute the results within the ratiopharm group and at Merckle?
 - Statistical overview of 2005/2006
 - On-site assessments – Criteria for the three observation levels
 - My personal observation hit list – critical observation examples
 - Consequences and outlook
- Britta Rotte, Merckle, Germany*

The situation on GMP- and regulatory compliance for APIs manufactured in China

- Overview of pharmaceutical and API industries in China
 - API manufacturers: licensed companies vs. chemical companies
 - Registration and inspection
 - Current and future GMP standards / Role of ICH Q7A
 - Minimizing risk in the global API supply chain
 - Which actions should be taken?
- Yueping Sun, Beijing CHNMED Pharmaceutical Consulting Co. Ltd., China*

Joint GMP and Regulatory Affairs Day

Parallel Sessions I

Session 1: Third Party Auditing – Experience Report from an Auditee

Vitalijs Skrivelis, Grindeks, Latvia

Session 2: API GMP Certification – The role of quality agreements for APIs including contract manufacturing

- Essential elements in a Quality Agreement for APIs with reference to ICH Q7A
- What are the roles and responsibilities of the contract giver and receiver
- Implications of the 2002/27 Directive for API certification to quality agreements
- How do QPs of contract manufacturers ensure compliance with the above in complex supply chains, especially if the contract giver also supplies APIs

Kathleen Wessberg, Abbott, USA

Session 3: Practical examples “Implementation of Q10”

- DSM Anti-Infectives Approach to implementation of Q10 .
- Gap Analysis based on current Quality Systems at Corporate and Manufacturing Site Level.
- Identification of Core Quality System Elements.
- Buy In of Top Management
- Implementation Plan
- Practical Examples of Benefits

Tom Buggy, DSM Anti-Infectives, The Netherlands

Session 4: APIs for use in clinical trials

- Use of APIs in clinical trials and relevance of ICH Q7A
- Use of the ICH Q8, Q9 and Q10 and their relevance of APIs in clinical trials
- What is the expectation of the different world regulatory areas with respect to GMP compliance of APIs used in clinical trials
- How different levels of GMP compliance apply to APIs as they move through the different phases of clinical trials and what are the different problems that can be encountered at the different stages
- How do you control APIs used for clinical trials if they are manufactured in the same equipment and facilities as marketed APIs

Jordi Ruiz-Combalia, Bioiberica, Spain



Parallel Sessions II

Session 5: A Quality Risk Management Approach to API Manufacturing

- Recent events and their impact on industry/regulator thinking
- Dedicated facilities – what approach? Risk based/risk averse?
- Prospective and retrospective risk management at interfaces
- Working 24/7

Malcolm Holmes, GlaxoSmithKline, UK

Session 6: Quality by design – design of experiments

- What is involved in setting up a design of experiment
- Benefits and limitations of design of experiment
- The role of design of experiment in quality by design
- How design of experiment can support ICH Q9 and Q10
- Quality by design, design of experiment and innovation

Dan Pilipauskas, Pfizer, USA

Session 7: Good Storage and Transportation Practice for APIs

- Requirements – regulatory and product-specific
- Good Storage Practice – how to control compliance in the premises of all parties involved from API manufacturer through to the API customer
- Good Transportation Practice – How to control compliance on the route
- Good Distribution Practice – How to control compliance during the whole supply chain
- (Re-)Labeling and (re-)packaging: dos and don'ts
- Challenges on the 'road to destination' (climates, customs, bandits,...)
- How to get information (e.g. Nigeria/NAFDAC's Black List) and how to deal with it
- Inspectional aspects/experiences on storage and transportation
- Role of Third Party Auditing

Karl Metzger, Welding, Germany

Session 8: Dealing with the difficulties to define API Starting Materials

- Key Regulatory Guidelines – what should industry refer to?
- Key considerations for industry
 - Factors to consider in API SM selection
 - Impact of science and risk-based thinking, Quality by design

Neil Wilkinson, AstraZeneca, UK

New concepts in pharmaceutical quality assessment from an EU perspective

Susanne Keitel, BfArM, Germany

ICH Q10: The pharmaceutical industry embracing integrated quality management

- Status of the ICH Q10 Guideline
- How Q10 builds upon Q7 for API
- How Q10 applies across the product lifecycle
- How Q10 applies for outsourced operations
- How Q10 applies across API and drug product operations
- Opportunities to enhance regulatory processes with Q8, Q9 and Q10

Gerald Migliaccio, Pfizer, USA

Revision of the EU Variations Regulations

- Backgrounds, reasons and objectives regarding the new revision
- The revision process from 2006 to the present
- Current status
- Next steps
- What are the most important changes in the new Variations Regulations vs. the previous Regulations?

Nicolas Rossignol, European Commission, DG Enterprise & Industry, Belgium

API-related activities of EMEA's Quality Working Party

- Responsibilities and tasks of the QWP
- Membership of the QWP
- Interactions with other authorities and stakeholders
- Recently completed, running and upcoming API-related projects
- How PAT, Q8, Q9 and Q10 impact upon the QWP's approach

Jean-Louis Robert, EDQM/QWP Chairman, Luxemburg

Regulatory Affairs Conference

Objective

Regulatory Affairs (RA) can still be a complex area for API manufacturers. In the RA conference the major problems will be addressed e.g. regarding submission and implementation of changes and possible solutions will be discussed. EDQM's latest activities on inspections and on the CEP procedure will be highlighted and the new developments regarding EU guidance on genotoxic impurities will be presented. Additionally, an APIC representative will speak about APIC's view on the revision of the Variations Regulation

Impact of changes at the API site for manufacturer of medicinal products

- Recap on variations regulations
- Requirements listed in Annex I to 2001/83 as amended and differences in filings through DMF procedure (LOC to be included in Annex 6.11) and CEP procedure (CEP to be included in Annex 10)
- Example of changes that may impact the safety of the medicinal product (e.g. polymorph due to solvent change)
- Example of irrelevant changes that lead to variations without any added value
- Past experience with changes that were not notified, consequences, costs

Hendrik de Jong, Servier IRIS, France

Update in inspections and CEP procedure

- Explanation of current procedure (notification, minor changes)
- Current experience, most frequent changes
- Typical shortcomings when such changes are notified
- Current revision on variations regulations: expected impact on CEP procedure
- Current workload at EDQM
- Experience with inspections :
 - Are relevant changes systematically notified, or are frequent "omissions" detected.
- Typical shortcomings
- Q&A type presentation about changes, e.g.
 - When can industry implement changes
 - What are the most frequent questions received on the EDQM website

Corinne Pouget, EDQM, France

APIC's view on the revision of the Variations Regulation

Hilde Vanneste, Janssen Pharmaceutica, Belgium

Experiences with the implementation of the new EU guideline on Genotoxic Impurities

- Review of regulation
- Interpretation of regulation – applicability to existing products
- Issues with this regulation as written
- Questions from industry
- Possible impact of the Guidance in API industry
- Proposals for the future

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

Closing Remarks

Matt Moran

Speakers include:

Tom Buggy, DSM Anti-Infectives, The Netherlands
Chris Cullen, Irish Medicines Board, Ireland
Malcolm Holmes, GlaxoSmithKline, UK
Hendrik de Jong, Servier IRIS, France (Chair of the EUROPEAN PHARMACOPOEIA COMMISSION)
Susanne Keitel, BfArM, Germany
Francois-Xavier Lery, EMEA, UK
Karl Metzger, Welding, Germany
Gerald Migliaccio, Pfizer, US
Moheb Nasr, FDA, CDER-ONDQA, USA
Dan Pilipauskas, Pfizer, USA
Corinne Pouget, EDQM, France
Jean-Louis Robert, QWP Chairman, Luxemburg
Nicolas Rossignol, European Commission, DG Enterprise&Industry, Belgium
DIANA VAN RIET-NALES, National Institute for Public Health and Environment, The Netherlands
Britta Rotte, Merckle, Germany
Jordi Ruiz-Combalia, Bioiberica, Spain
Vitalijs Skrivelis, Grindeks, Latvia
Yueping Sun, CHNMED, China
Zofia Ulz, Main Pharmaceutical Inspectorate, Poland
Hilde Vanneste, Janssen Pharmaceutica, Belgium
Kathleen Wessberg, Abbott, USA
Neil Wilkinson, AstraZeneca, UK

Chairmen

Mr Anthony Storey, Pfizer, UK
MR MATT MORAN, Pharma Chemical Ireland
MS NESSA MOYLES, Pharma Chemical Ireland

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 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? And have your company listed in the conference programme? Please contact Ms Marion Grimm, phone +49-62 21 / 84 44 18, grimm@concept-heidelberg.de

Social Event on 24 October

The social event has become a tradition and was well appreciated during the past conferences (in Brussels, Hamburg, Vienna, Barcelona, Budapest, Lisbon, Berlin and Prague). We will continue this tradition in Warsaw and invite all participants and speakers to an entertaining evening outside the hotel followed by a dinner.



Registration

Tuesday, 23 October 2007, 19.00 - 20.00 h or
Wednesday, 24 October 2007, 09.00 h - 10.00 h
Regulatory Affairs Part: Thursday, 25 October 2007, 08.00-08.30 h

Conference

Wednesday, 24 October 2007, 10.00 h - 18.00 h
Thursday, 25 October 2007, 08.30 h - 17.45 h
Friday, 26 October 2007, 09.00 h - 14.00 h

Venue

Hilton Warsaw Hotel and Convention Centre
Pre-Opening office: ul. Grzybowska 63
00-844 Warsaw, Poland
Phone: +48 (0) 22 356 55 55 Fax: +48 (0) 22 356 55 56

Fees

Book the GMP Part (24-25 October) or the Regulatory Affairs Part (25-26 October) separately for the price of € 1,590.00 each. Or book all three conference days for the special price of € 1,890.00. 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 has reserved a limited number of rooms in the Hilton Hotel. Reservation should be made directly with the hotel not later than 23 September 2007. Be sure to mention CONCEPT to receive the specially negotiated rate for the duration of your stay. 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

CONCEPT HEIDELBERG
P.O. Box 10 17 64, 69007 Heidelberg, Germany
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info@concept-heidelberg.de, www.concept-heidelberg.de

Dr Gerhard Becker (phone + 49 (0) 62 21 / +84 44 65, becker@concept-heidelberg.de) the responsible Operations Director, will help you with any questions as regards content. Ms Marion Grimm (phone + 49 (0)62 21 / 84 44 18, grimm@concept-heidelberg.de), the responsible organisation manager, will help you with any questions concerning reservation, hotel, etc.

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)!**

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

10th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

24 - 26 October 2007, Warsaw, Poland

I want to take part in

- GMP Part (24-25 October 2007)**
 Regulatory Affairs Part (25 - 26 October 2007)
 All three conference days (24-26 October 2007)

Please choose 2 out of 8 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 Session I

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Session 1: Third Party Auditing - Experience report from an auditee |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 2: API GMP Certification - The role of quality agreements for APIs including contract manufacturing |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 3: Practical examples "Implementation of Q10" |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 4: APIs for use in clinical trials |

Parallel Session II

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Session 5: A Quality Risk Management Approach to API Manufacturing |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 6: Quality by design - design of experiments |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 7: Good Storage and Transportation Practice for APIs |
| <input type="checkbox"/> | <input type="checkbox"/> | Session 8: Dealing with the difficulties to define API Starting Materials |

Mr Ms Title _____

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First name, surname

Company

APIC Member Inspectorate

Department

Important: Please indicate your company's VAT ID Number

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E-mail (please fill in)