



EFCG

EUROPEAN FINE CHEMICALS GROUP

Speakers and Panel Discussion Delegates

Sabine Atzor

*European Commission,
Belgium*

Lynne Byers

EFPIA, Belgium

Susanne Keitel

EDQM, France

Georgette Lalis

*European Commission,
Belgium*

Philippe André

*Tianjin University,
China*

Arnulf Heubner

Merck, Germany

Frithjof Holtz

Merck, Germany

Winfred Kooij

*Dutch Customs,
The Netherlands*

Julie Maréchal

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Iain Moore

*IPEC Europe, Croda,
United Kingdom*

Guy Villax

Hovione, Portugal



4th EFCG Pharma Business Conference

Strategies for Compliant Pharma Sourcing

How regulators, producers and users are meeting the
challenges of globalisation



13-14 May 2009, Brussels, Belgium

4th EFCG Pharma Business Conference – Strategies for Compliant Pharma Sourcing

Brussels, Belgium, 13-14 May 2009

Objectives

The 3rd EFCG Pharma Business Conference, held in Lisbon in May 2008, formed an important milestone in the discussions on the full implementation and enforcement of the new API-related legislation and on the possibilities to protect the patients in EU member states against unsafe counterfeit and rogue APIs and excipients.

The 4th EFCG Pharma Business Conference will bring together the key policy and decision makers and major industry stakeholders to discuss the latest regulatory and legislative initiatives that are expected to have a large impact on the global trading and sourcing of pharma raw materials. Furthermore, key proposals for excipients certification and risk classification will be presented.

The topics to be presented and discussed will include:

- The draft EU Directive on „counterfeit medicines“
- Aspects of international cooperation on API inspections
- Customs' view regarding control of API imports into Europe
- The API manufacturing situation in China
- High-level panel discussion on APIs
- Risk classification approaches for excipients
- A proposed European Excipients Certification scheme

The conference will include discussions on key aspects of controlling the manufacture and distribution of the widely used Common Excipients with special focus on a European certification scheme. These substances contribute by far the largest weight and volume in most pharmaceutical finished dosage forms.

Target Group

The conference addresses the ingredients supply chains for human and for veterinary medicines, from the producer of raw materials to the user of raw materials.

The conference is designed to promote an inter-disciplinary dialogue by selecting issues that are common to different company functions that may in part have conflicting agendas.

We plan to bring together (senior) pharma business executives, Qualified Persons, QA, RA and purchasing managers as well as EU regulators and inspectors. Executives in general management positions will be able to better understand the issues at stake as a result of the increasing enforcement of compliance and quality.

Programme

Session 1: Active Pharmaceutical Ingredients

■ The Safety Gap

- A critical view on the globalisation of pharmaceutical ingredients manufacture

■ The Draft EU Directive on “Counterfeit Medicines”

In December 2008 the Commission has adopted a legal proposal on counterfeit medicines which is currently subject to discussions at the Council and the European Parliament. It includes amendments of the Community legal framework on pharmaceuticals with respect to the following 3 pillars:

- Product characteristics and GMP
- Actors in the supply chain and GDP
- Active substances

■ API Inspections

- Inspections in the framework of EDQM's Certification Scheme
- Criteria for selection of inspection sites
- International cooperation in API inspections: the pilot programme
- Future developments

■ A Customs View on what is Needed to Control API Imports into Europe

- The control of APIs in transit and patent protection

■ API Manufacturing Situation in China – an Auditor's Experiences and Views

- API manufacture in China
- View on the safety of the supply chain of APIs in and from China
- What is needed to secure the safety of APIs originating from China?
- How will current content of the Draft Directive improve the situation?
- Are there alternatives and/or better approaches to secure the safety of APIs coming from China

Panel Discussion

Delegates from the European Commission, EDQM and different industry sectors will discuss the API-related content of the Draft Directive

Session 2: Excipients Certification Initiative – Global Status and Regional Specifics

■ Excipients Certification Scheme

- Excipient Classification
- An auditable GMP Standard
- An auditable GDP standard
- A definition of 3rd party auditor competency and training requirements
- Certification scheme rules and agreements for 3rd party auditors and participants

■ Risk Classification of Excipients – Current Status and Concept

- Why classification of excipients
- Three level GMP concept
- A tool for excipient manufacturer and excipient user
- Next steps

■ Excipients Certification: GMP and GDP Aspects

Panel Discussion

This panel discussion will focus on key aspects of the proposed Excipients Certification Scheme

Chairman

Arnulf Heubner

Merck KGaA, Germany and Chair of the EFCG Pharmaceuticals Business Committee

Steering Committee

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

Chris Oldenhof, DSM Anti-Infectives, The Netherlands

Pieter van der Hoeven, EFCC, Belgium

Guy Villax, Hovione, Portugal

Arnulf Heubner, Merck KGaA, Germany

Gerhard Becker, CONCEPT HEIDELBERG, Germany

Oliver Schmidt, CONCEPT HEIDELBERG, Germany

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Social Event

On Wednesday, 13 May, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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 EFCG



EFCG was launched as a sector group of CEFIC in 2004 to deal with common business and political issues affecting European fine chemicals producers.

APIC – the Active Pharmaceutical Ingredients Committee – provides its technical leadership. EFCG's vision is to sustain value creation for its members through competitiveness, growth and environmental performance, and that this is recognised by society. EFCG's mission is to be the voice, the focus and the forum of the fine chemicals industry in Europe.

About CONCEPT HEIDELBERG

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

Conference Exhibition

During this EFCG conference you have the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490.- Please contact Dr Gerhard Becker (phone +49 62 21-84 44 65; e-mail: becker@concept-heidelberg.de) or Ms Susanne Ludwig (phone +49 62 21-84 44 44; e-mail: ludwig@concept-heidelberg.de).

Venue 2009

The City

Brussels is the capital of Belgium and the administrative centre of the European Union. This has earned the city the title of the Capital of Europe. Brussels has been given its character by the coexistence of French and Flemish culture, and it is nowadays home to nationalities around the world, adding a cosmopolitan flavour to its atmosphere. The vibrant atmosphere of Brussels is further enhanced by picturesque medieval streets, lively squares, beautiful boulevards, impressive monuments, spacious parks, cosy cafés, interesting restaurants and an active cultural life.

To learn more about the Belgian capital, you may also want to visit <http://www.brussels.org/>.

Places of Interest

No matter what you are interested in, as an international metropolis Brussels has lots of attractions. The city is a mosaic of languages, cultures, and traditions. Aside from the splendid and varied



architectural styles of the city, Brussels also hosts over 80 museums, numerous tourist attractions, a vibrant night-life, and more restaurants than you could count.

Transportation

Please visit <http://www.brusselsairport.be/> for more information on the Brussels International Airport. A brochure with major information on accessibility, assistance, arrival and departure as well as on shops, bars and restaurants and more is available in English at <http://www.brusselsairport.be/en/content/brochures/272120>.

The Hotel - The Hilton Brussels

In the heart of Brussels the Hilton Brussels hotel is 5 minutes from the city's attractions. Dine on French cuisine at the Maison de Boeuf restaurant. Pamper yourself with a facial or massage at the health. Marvel at the Atomium, entertain the kids at Oceade Water Park or roam UNESCO World Heritage Site, Grande Place. After a day enjoying Brussels attractions, unwind in the Hilton Brussels hotel's sauna. Indulge in French cuisine at Maison du Boeuf restaurant. Sip cocktails at the Hilton Brussels hotel's Le Bar. 5 minutes' walk to the commercial district and 10 minutes' drive to the European Commission, the Hilton Brussels hotel has 20 meeting rooms, Executive Lounge and business center. From Deluxe Rooms to Suites, all Hilton Brussels hotel rooms have wireless internet access. Suites and Executive Rooms offer Executive Lounge access.

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.efcg-conference.org

Date

Wednesday, 13 May 2009, 10.00 – 17.30 h
Thursday, 14 May 2009, 09.00 – 12.00 h
Registration: Wednesday, 13 May 2009, 9.00 – 10.00 h

Venue

Hilton Brussels
Boulevard de Waterloo 38
1000 Brussels, Belgium
Phone +32 (0) 2504 3730
Fax +32 (0) 2504 3750

Conference fees

The conference fee is € 1,690.- per delegate plus VAT.
Reduced participation fee for EFCG Members: € 1,521,- per delegate plus VAT.
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

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 booking code CONA110509 to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 15 April 2009. Early reservation is recommended.

Registration

You can either register via the attached reservation form, by E-Mail or by fax, or you can register online at www.efcg-conference.org. Your registration will be confirmed by E-Mail.

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:

Dr Gerhard Becker (Operations Director) at +49-62 21/84 44 65, or by e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Susanne Ludwig (Organisation Manager) at +49-62 21/84 44 44, or by e-mail at ludwig@concept-heidelberg.de.

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

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

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

4th EFCG Pharma Business Conference: Strategies for Compliant Pharma Sourcing

13-14 May 2009, Brussels, Belgium

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
 - until 2 weeks prior to the conference 10 %
 - until 1 weeks prior to the conference 50 %
 - within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel 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 HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!