Strategies against Counterfeit Medicines
Implementation of Counterfeit Protection Systems in the Pharmaceutical Industry

26 - 28 April 2010, Würzburg (near Frankfurt), Germany

SPEAKERS:

Nimo Ahmed, MHRA, UK
Patricia Blanco, ETCO, Brazil
Hugo Bonar, Irish Medicines Board, Ireland
Andy Charvill, MHRA, UK
Frederick L. Fricke, FDA, USA
Jean-Michel Guirado, Amgen, The Netherlands
Prof Dr. Ulrike Holzgrabe, University of Würzburg, Germany
Dr Dries de Kaste, RIVM, The Netherlands

Dr Sabine Kopp, WHO, Switzerland
Dr Thomas Lenhard, sanofi-aventis, Germany
Dr Chris Oldenhof, DSM Anti-Infectives, The Netherlands
Dr Jim Rittenburg, Authentix Inc., USA
Dr Stephan Schwarze, Bayer Schering Pharma AG, Germany
Janice M. Soreth, US FDA’s Europe Office, UK
Nathalie Tallet, sanofi-aventis, France
Dr Christian Tillmanns, meyer//meisterernst Rechtsanwälte, Germany

HIGHLIGHTS:

- Regulatory Updates
  - WHO’s Anticounterfeiting Programme and IMPACT
  - EU Directive on Counterfeit and the Council of Europe’s Draft Convention
  - MHRA (UK) Anticounterfeiting Strategy
  - FDA’s Activities
  - Legal Obligations and Implications for the Pharmaceutical Industry
- The Pharmaceutical Tracing and Authentication System in Brazil
- Analytical Detection of Counterfeit Drugs
  - Advanced Forensic Techniques at FDA’s Forensic Chemistry Center
  - Role of the MHRA (UK) Anticounterfeiting Laboratory
  - NIR and Raman Spectroscopy at the RIVM (NL) Laboratory
  - Missions and Role of Sanofi-Aventis’ Testing Laboratory
- Falsified APIs: Are we solving the problems?
  - Experiences from EFPIA’s Pilot in Sweden for Coding and Identification with 2D Data Matrix Code
  - Supply Chain Integrity
  - Means, Measures and Tools to Protect a Pharmaceutical Product
Invitation by the University of Würzburg

Dear Colleagues,

It is a great pleasure for me to invite you to the International Conference "Strategies against Counterfeit Medicines" in Würzburg. After a first successful conference in November 2008, this is the second conference on this topic supported by the University of Würzburg.

Counterfeit APIs and medicines pose a growing threat to patients worldwide, with increasing numbers in Europe and the USA. Customs all over the world find more and more illegally produced drugs. And drugs are increasingly sold via the internet making it much easier to put counterfeits into circulation.

Thus, strategies against counterfeited medicines become more important. With this in mind, our new conference programme will focus on:

- Regulatory updates from WHO/IMPACT, FDA, EU (European Commission’s approach and the Council of Europe’s draft convention on counterfeit medical products), and the pharmaceutical tracing and authentication system in Brazil
- Analytical methods and laboratories to detect counterfeit products (e.g. FDA’s Forensic Chemistry Center)
- Supply chain security for APIs and medicinal products

The aim of this event is to provide a platform for interesting and interactive discussions with regulatory authority representatives, industry experts, university colleagues and delegates from suppliers of anti-counterfeiting products and systems to exchange experiences on the various aspects of anti-counterfeiting activities.

It will be a great pleasure for me to welcome you in Würzburg on behalf of the Institute of Pharmacy and Food Chemistry of our university.

Prof. Dr. Ulrike Holzgrabe
Chair of Pharmaceutical Chemistry
University of Würzburg

This conference is supported by

The University of Würzburg
With over 600 years of tradition, the Julius Maximilian University of Würzburg is today one of Germany’s mid-sized universities. 400 professors in 10 faculties here teach roughly 20,000 students. The University of Würzburg is among the leading institutions of higher education in Germany; this has been confirmed by rankings carried out by national and international research organizations, international external assessment committees as well as by the German Federal and State Excellence Initiatives (founded in 2006). Internationally, the University of Würzburg is also one of the top-ranking academic institutions in many fields of research and study.

The German Pharmaceutical Society (Deutsche Pharmazeutische Gesellschaft)
The German Pharmaceutical Society (DPhG), founded in 1890 in Berlin, is one of the oldest German scientific societies (9,000 members). The aims of the DPhG are to promote the pharmaceutical sciences and interdisciplinary way of thinking, to encourage junior scientists within the pharmaceutical community, to maintain contact with foreign scientists and with foreign special societies, to facilitate transfer of new scientific knowledge into pharmacy practice, to advise legislative and administrative bodies on pharmaceutical matters and to establish position statements on pharmaceutical questions of public interest.

The European QP Association
The Qualified Person Association was founded on 7 July 2006 with the objective to represent the Qualified Persons in Europe. Within only 10 weeks, more than 350 QPs and individuals preparing to become a QP from all over Europe already signed up for membership. The members represent all major pharmaceutical companies as well as small and medium-sized businesses. In addition to QPs from EU member states, QPs from EU member candidates and proposed candidates can also become members/associate members. „Guest“ and „Observer“ are additional membership status levels available to applicants from other countries who may be involved in the certification and batch release of medicinal products.

Exclusive Media Partner: SecuringPharma.com
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.

Target Audience

This conference is intended for people working in
- Packaging Development
- R&D
- Manufacturing / Packaging
- Quality Assurance / Quality Control (QPs)
- Purchasing and Materials Management
- Regulatory Affairs
- Counterfeit Protection Management

of pharmaceutical, biopharmaceutical and API companies. The conference is also intended for members of national or international authorities and for personnel working in Security Technology, and Packaging Components or Labelling companies.
Objectives

The aim of this conference is to present both the regulatory authorities’ activities and the pharmaceutical industry’s activities to develop and establish appropriate counterfeiting protection systems. The conference will focus on effective and affordable strategies, improve collaboration among regulators and pharmaceutical industry, and discuss actions in the global fight against counterfeit.

Background

According to the European Medicines Agency (EMEA) and the World Health Organisation (WHO) counterfeit medicines are manufactured wilfully outside the scope of any established standards of safety, quality and efficacy and their corresponding control mechanism. They are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients or with insufficient active ingredients.

Industry and regulators are equally concerned about the rise in counterfeit drugs which are increasingly present even in better controlled markets.

At the end of 2008 the European Commission made a legal proposal to combat counterfeits: there is an alarming increase in the EU of falsified, illegal medicinal products, which pose a major threat to European industry and European patients. There is a clear need for the Commission to act now!

In January 2009 the FDA (CDER and ORA) announced a voluntary Secure Supply Chain Pilot Program for finished drug products and APIs. This program will assist FDA in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs. In addition FDA issued two Draft Guidelines for Industry in 2009:

- Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting (July 2009)

It is the aim of this conference to inform participants about the latest regulatory requirements (WHO, EU, EMEA, FDA, Brazil, etc.) and the measures the pharmaceutical industry has to take to combat counterfeit medicines.

Moderator

Prof Dr Ulrike Holzgrabe
University of Würzburg, Germany

Programme

Session 1: Regulatory Updates

Introduction to the Conference
- Different forms of counterfeiting
- Representative cases
- Production in China and India
- Control of the supply chain
- Drugs and Internet

Prof Dr Ulrike Holzgrabe, University of Würzburg

Update on WHO’s Anti-counterfeiting Programme and IMPACT
- Problem of counterfeit medicines first addressed at the international level in 1985
- WHO studies the feasibility of setting up a clearing house to collect data and to inform governments about the nature and extent of counterfeiting
- Resolution WHA41.16 to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations
- Resolution WHA47.13 to assist Member States in their efforts to ensure that available medicines were of good quality, and in combating the use of counterfeit drugs
- WHO’s launch of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in 2006
- An update will be given on recent events and activities of WHO and IMPACT

Dr Sabine Kopp, WHO, Switzerland

How the European Region is Responding to the Counterfeiting of Medical Products and Similar Crimes
- The European Commission’s approach to falsified medicinal products having regard to its dual function of medicinal product regulation for trade and the protection of public health
- The Council of Europe’s draft Convention on Counterfeit Medical Products and Similar Crimes: a Human Rights approach through the Criminal Law to protect public health

Hugo Bonar, Irish Medicines Board, Ireland

FDA’s Anti-Counterfeit Strategies – Update and Future Activities
- FDA Strategy how to handle counterfeit products on the market and how to prevent counterfeit medicines in the future
- Current Status of the FDA Pilot Program “Secure Supply Chain”
- Pedigree
- Traceability
- Overview of relevant FDA guidance
- Draft Guidance for Industry “Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anti-counterfeiting”

Janice M. Soreth, US FDA’s Europe Office, London, UK
The Pharmaceutical Tracing and Authentication System in Brazil
The pharmaceutical tracing and authentication system is now a reality in Brazil, but is also a huge challenge, especially because the market complexity and country dimension. Believing that it was necessary to proof the concept and also to provide greater security in the implementation phases, ETCO offered the possibility to run a pilot project and signed in December ’09 with ANVISA a technical agreement and started the pilot project with: Pfizer, Bayer, Sanofi-Aventis, Nycomed and three important local companies: Eurofarma, Ache and Mantecorp.

Patricia Blanco will show the Brazilian experience and share with the participants the results and findings of this test.

Traceability and Authentication – The Brazilian Project Pilot
- Diagnosis of Informality in Pharmaceutical Industry in Brazil
- Requirements of the System
- System design
- The Act 11.903 /09 – the Brazilian Law of traceability
- The Project Pilot
- Results and findings
- Up Date
- Conclusions

Patricia Blanco, ETCO, Brazil

MHRA (UK) Anticounterfeit Strategy
- Set-up and activities of the MHRA Enforcement Group
- Skills required of an investigator
- Aim of strategy is to minimise the risk of counterfeit medicines reaching patients in the UK or being sent from/through the UK
- Political, strategic and operational initiatives employed by the MHRA with stakeholders in the UK and overseas
- Vigilance measures required across the supply chain

Nimo Ahmed, MHRA, UK

Counterfeit Protection Management in the Pharmaceutical Industry: Legal Obligations and Implications
- Criminal Liability
- Pharmaceutical Products Liability for damages caused by counterfeit medicines
- Responsibilities of the manufacturers/distributors
- Legal instruments against counterfeit products
- Upcoming regulations in the EU – „Pharmaceutical Package”

Dr Christian Tillmanns, meyer//meisterernst Rechtsanwälte, München, Germany

The Role of the Laboratory in the Support of the MHRA Anti-Counterfeiting Strategy
- Combating counterfeit medicines
- Market surveillance
- Laboratory confirmation of counterfeits
- Comparison with authentic comparators
- Spectroscopic, chromatographic and novel techniques

Andy Charvill, MHRA, UK

Industry Case Study: sanofi-aventis’ Counterfeit Testing Laboratory in Tours
- sanofi-aventis’ approach to fight counterfeit drugs
- Internal management
- Missions and role of the central laboratory

Nathalie Tallet, sanofi-aventis, Tours, France

Elucidation of Counterfeit Drugs
- Terminology (as the terminology used in public media related to counterfeit and illegal medicines is confusingly mixed up, the differences in legal position and practical implications for the laboratory activities for these two categories will be shortly explained)
- Legal status
- Detection of counterfeit drugs
- Overview of the current laboratory practice in a governmental laboratory in charge of the investigations for the various inspection services (Health Authorities, Customs, Police)
- NIR and Raman spectroscopy
- Practical examples of recent cases discussing the legal aspects as well as the use of the different available techniques

Dr Dries de Kaste, RIVM, The Netherlands

Session 3:
Supply Chain Security for APIs and Excipients

Falsified APIs: Are we Solving the Problems?
- Magnitude of the problem
- Overview of progress since „Würzburg 2008”
- Situation in Europe / API aspects of the Directive on Falsified Medicines and other initiatives
- Situation in the USA / Drug Safety Bill and FDA’s initiatives
- Developments in Asia
- Are Falsified APIs still reaching the patients today?
- The way forward

Dr Chris Oldenhof, DSM Anti-Infectives, The Netherlands

RX-360 – A New Approach for a Secure Supply Chain
- Weaknesses & un-met needs of the current pharmaceutical supply chain
- Rx-360 vision & mission
- The Value proposition – a “win-win” approach for all interested parties
- The Four Distinct Functions of the Consortium
- The foundations of the audit model
- Why standards are required
- The benefits of monitoring
- The criticality of technology in securing the supply chain
- Current status of Rx-360 and how it will grow
- How you can join

Jean-Michel Guirado, Amgen, The Netherlands
Session 4: Supply Chain Security for Medicinal Products

EFPIA’s Proposal for Coding and Identification with 2D Data Matrix Code – Experiences from the Pilot in Sweden
- Context of coding in Europe and beyond
- Key elements
- Pilot in Sweden and obtained results
- Alternatives?
- Next steps

Dr Stephan Schwarze, Bayer Schering Pharma AG, Germany

Supply Chain Integrity – Product QA Down to the Patient
- What does it mean: safeguard product quality and integrity along the supply chain?
- What major requirements need to be considered?
- How to keep control on target KPIs / current strategies and methods?
- Where are we today and where to go?

Dr Thomas Lenhard, sanofi-aventis, Germany

Means, Measures and Tools to Protect a Pharmaceutical Product from Secondary Packaging to the Product itself
- Authentication Technology Selection
- Technology Layering
- Security Feature Management
- Authentication/Serialization
- Secure Supply Chain
- Security Program Implementation and Management
- Technology Insertion
- Minimizing Impact to Manufacturing Processes

Dr Jim Rittenburg, Authentix, USA

Speakers

Nimo Ahmed, MHRA, UK
Nimo plays a leading role in the Agency’s UK Medicines Anti-Counterfeiting strategy and has spoken all over the world on the subject of counterfeit medicines. He also represents the MHRA and the UK on a number of international forums. Prior to joining the MHRA, Nimo spent seven and a half years as an Army officer during which time he was deployed on four overseas operational tours of duty, where two roles saw him employed as an Intelligence Officer.

Patricia Blanco, ETCO, Brazil
Patricia Blanco is the Executive Director of ETCO – Brazilian Institute for Ethics in Competition, a non-profit organization that congregates non-government and entrepreneurial institutions formed by the breweries, soft drinks, tobacco, fuel distributing, medical drugs and technology industries that aims to establish ethical parameters for competition. They are currently working with ANVISA (The Brazilian Government Agency in charge of health related activities) on the tracking and authentication system of medical drugs.

Hugo Bonar, Irish Medicines Board, Dublin, Ireland
Hugo is the Enforcement Manager of the Irish Medicines Board with responsibilities in the areas of both medicines and medical devices. He has degrees in Law and in Public Administration. He is a qualified Attorney-at-Law (New York). He is the former Chair of the Heads of Medicines Agencies Working Group of Enforcement Officers and a member of the Management Committee of the Permanent Forum on International Pharmaceutical Crime.

Andrew John Charvill, Analytical Assessor, Medicines Testing Scheme, MHRA, UK
Andy Charvill is a chemist by training and has worked at the Medicines and Healthcare products Regulatory Agency (MHRA), the UK Competent Authority, as the Analytical Assessor for the Medicines Testing Scheme (MTS), since 1994. Prior to this Andy was employed in a variety of Quality Control/Quality Assurance positions in the Pharmaceutical Industry, principally in the manufacture of Large Volume Parenterals.

Frederick L. Fricke, Director, Forensic Chemistry Center, U.S. Food and Drug Administration (FDA), Cincinnati, OH, USA
In 1962, Mr. Fricke joined the FDA as a chemist. He was appointed as National Expert in Emission Spectroscopy in 1978. In 1980, he was selected for the position of Director of the Office of Regulatory Affairs - Elemental Analysis Research Center. In 1990, he was named Director of FDA’s Forensic Chemistry Center in Cincinnati. As Director, Mr Fricke is responsible for the direction and coordination of all activities for the Forensic Chemistry Center. He established and is currently a member of the International Laboratory Forum on Counterfeit Medicines. This Forum is a collaborative effort with scientists from England, Germany, Australia, Canada, Singapore, Austria, Switzerland, the Netherlands, and the United States to detect counterfeit and unapproved pharmaceuticals.

Jean-Michel Guirado, Amgen, The Netherlands
Jean-Michel is Senior Manager Brand Protection at Amgen since October 2008 in Breda, The Netherlands. He is responsible for the Brand Protection program for Amgen’s international markets. He also represents Amgen in the Anti-Counterfeiting Ad Hoc Working Group of EFPIA. Engineer in Materials Physics by education, Jean-Michel Guirado has over 12 years of experience in the pharmaceutical industry within various functions in Process Development and Medical Device Engineering. Prior to his positions in the pharmaceutical industry, Jean-Michel has had managerial responsibilities for Product Development, Project Management, Process Validation and Quality in the automotive industry.

Prof Dr Ulrike Holzgrabe, University of Würzburg, Würzburg, Germany
Ulrike Holzgrabe holds a chair in Pharmaceutical Chemistry at the University of Würzburg and is a member of several national an international committees dealing with the German and European Pharmacopoeia. Thus, she is interested in modern analytical methods for quality assurance of drugs.
Dr Dries de Kaste, RIVM, The Netherlands
Dr Dries de Kaste, pharmacist by training, is head of the governmental laboratory responsible for the quality control of medicines and the analysis of counterfeit drugs. He is a member of the Dutch delegation of the European Pharmacopoeia Commission.

Dr Sabine Kopp, World Heath Organization (WHO), Geneva, Switzerland
Sabine Kopp, Ph.D., has worked in various positions within the WHO, including Secretary for the International Nonproprietary Names (INN) Programme, Acting Team Coordinator for Quality Assurance and Safety of Medicines, in the Department of Essential Drugs and other Medicines. She is Secretary of the WHO Expert Committee on Specifications for Pharmaceutical Preparations and is responsible for the normative work related to Drug Quality Assurance within WHO. Dr Kopp is Programme Manager of the WHO Medicines Quality Assurance and Anti-Counterfeiting Programmes. In addition she acts as Secretary ad interim of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

Dr Thomas Lenhard, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany
Dr. Lenhard joined one of the Sanofi-Aventis predecessor companies in the area of quality control for development products in 1986. He made the next steps during his professional career by taking responsibility for various managerial positions within the local and global quality control, quality assurance and supply chain functions. Since 2005 he is in charge of Quality at the site Distribution Platform Frankfurt, DP FRA, within the Sanofi-Aventis Deutschland GmbH.

Dr Chris Oldenhof, DSM Anti-Infectives, Delft, The Netherlands
Chris Oldenhof holds a Ph.D. in organic chemistry. He is currently Manager External Regulatory Affairs at DSM, Delft, The Netherlands. In his 30 years with DSM he has held positions in R&D, Marketing & Sales and Regulatory Affairs. Within CEFIC (European Chemical Industry Council) he is the President of APIC (Active Pharmaceutical Ingredients Committee) and a Board Member of the EFCG (European Fine Chemicals Group). In addition, on behalf of APIC, he is a member of the Council of Europe’s ad hoc Working Group on Counterfeit Medicines since its foundation in 2003.

Dr James H. Rittenburg, Authentix Inc., USA
Dr Rittenburg joined Authentix in 1994 and is currently Vice President of the company’s Healthcare and Life Sciences division. He has over 25 years experience developing diagnostic systems for detecting trace levels of chemicals in samples including pharmaceuticals, foods, beverages, petrochemicals, and agricultural products. He has edited several books, authored numerous journal articles and is an inventor on a number of patents in this field. Dr. Rittenburg has worked with many of the leading pharmaceutical manufacturers to design and implement product security systems. Prior to joining Authentix, Dr. Rittenburg was Director of Product Development for Quantix Systems.

Dr Stephan Schwarze, Bayer Schering Pharma AG, Berlin, Germany
Stephan Schwarze holds a Ph.D in pharmaceutical technology. He started his career in 1992 at Schering AG Berlin. During his professional career he worked in several areas at different management levels as for instance R&D of contrast media, manufacturing of solids and parenterals and as personal assistant to a member of the board. He is heading the function Counterfeit Protection Management, first within Schering and nowadays within Bayer Schering Pharma. This function was established in 2005 and since then developed by him. He is a member of WHO IMPACT’s Technology Subgroup as well as of EFPIA’s Anti-Counterfeiting ad hoc working group.

Janice M. Soreth, US FDA’s Europe Office, London, UK
Janice Soreth is Deputy Director of the US FDA’s Europe Office, coordinating FDA activities in Europe for medical products (human and veterinary drugs, biologics, and devices). She is seconded to the European Medicines Agency and resides in London. She directed FDA’s Division of Anti-Infectives and Ophthalmology from 2000-2007 and served as a general internist in the US Public Health Service.

Nathalie Tallet, sanofi-aventis, Tours, France
Nathalie Tallet is Head of the Anti Counterfeiting Central Laboratory of Sanofi-Aventis group since September 2007 in Tours, France. She has a Master Degree in Manufacturing Healthcare Products and Pharmaceutical Development from Pharmaceutical Sciences University, Bordeaux, France and has worked at Sanofi-Aventis since 1993 in various roles in co-ordination of pharmaceutical activities.

Dr. Christian Tillmanns, meyer//meister Rechtsanwälte, Munich
Dr. Christian Tillmanns is a lawyer specialized in pharmaceutical and medical devices law. After traineehips in the legal departments of pharmaceutical companies as SmithKline Beecham (Glaxo) and Pfizer as well as in the pharmaceutical law department of an international law firm and more than 6 years practise in the law firm Kaltwasser Rechtsanwälte (specialized Advisors in pharmaceutical and health care law) he joined the Munich law firm meyer//meister-ernst in the beginning of 2008. Dr. Tillmanns supports companies in all questions concerning pharmaceutical law (regulatory and marketing affairs), including representing the clients in legal proceedings (particularly in unfair competition and pharmaceutical advertising law).

Social Event

On the evening of the first conference day, you are cordially invited to a social event in the historical city of Würzburg. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.
Organisation and Contact

CONCEPT HEIDELBERG
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Dr Günter Brendelberger (Operations Director) at +49-6221/84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager) at +49-6221/84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.

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.

ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidelines.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years - free of charge. There are no obligations for the member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website http://www.gmp-compliance.org.

Würzburg – Accessibility via Frankfurt Airport

The transfer from Frankfurt Airport to Würzburg is rather convenient:

1. By Bus Shuttle

There will be a bus shuttle free-of-charge from Frankfurt Airport to the Maritim Hotel Würzburg on Sunday, 25 April 2010, at 20.00 h and on Monday, 26 April 2010, at 10.00 h. Travelling time approx. 2 hours.

On Wednesday, 28 April 2010, buses will transfer for Frankfurt Airport directly after the end of the conference. Travelling time: approx. 2 h.

2. By Train

Alternatively, there is a direct 1 h 30 min train connection from Frankfurt Airport to Würzburg Main Station.
Date

Monday, 26 April 2010, 13:30 – 18:30 h
(Registration and coffee 12:30 – 13:30 h)
Tuesday, 27 April 2010, 08:30 – 18:30 h
Wednesday, 28 April 2010, 08:30 – 15:30 h

Venue

Maritim Hotel Würzburg
Plechertorstr. 5
97070 Würzburg (near Frankfurt)
Germany
Tel.: ++ 49 / (0) 931 / 3053-0
Fax: ++ 49 / (0) 931 / 3053-900 / -901

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the event 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 “ECA-CON 250410” to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 25 March 2010. Early reservation is recommended.

Reservation Form (Please complete in full)

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26 - 28 April 2010, Würzburg, Germany

Mr   Ms

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number

Important: Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

City                        Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

Fees

Non-ECA Members EUR 1,990.- per delegate plus VAT
ECA Members EUR 1,791.- per delegate plus VAT
APIC Members EUR 1,890.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates EUR 995.- 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 the 2nd and 3rd day and all refreshments. VAT is reclaimable.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.counterfeit-conference.org.

Conference language

The official conference language will be English.

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!

Internet:
www.gmp-compliance.org
www.counterfeit-conference.org