ECA
European Compliance Academy

SPEAKERS

DR CHRISTOPHER BURGESS
Burgess Analytical Consultancy, United Kingdom

TREVOR COOMBER
Freelance Consultant, United Kingdom

PETER GASSMANN
Swissmedic, Switzerland

DR GERD JILGE
Boehringer Ingelheim, Germany

DR GEROLF TITTEL
LAT, Germany

IMPURITIES

Special focus on genotoxic impurities and heavy metals

Copenhagen, Denmark, 23 - 25 May 2012

HIGHLIGHTS:

- Practical Aspects of the Analysis of Impurities in Drug Substance and Drug Products
- Approach to Specifying Impurities through the Development Life Cycle
- Genotoxic Impurities – Detection, Control and Reporting
- Residues of Metal Catalysts and Reagents
- Residual Solvents
- Extractables and Leachables as Sources of Impurities
- Analytical Techniques for Detecting Impurities
- Genotoxic Impurities in Herbal Products
- Regulatory Issues of Data Presentation in the Common Technical Document

This conference is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager". Please find details at www.gmp-certification.eu

IMPURITIES

23-25 May 2012, Copenhagen, Denmark

Objectives

This conference will provide an opportunity to reinforce and expand your knowledge of the general area of impurities in chemical entities from initial development to the market with emphasis on

- Detection, profiling and control of impurities in drug substances, intermediates and drug products
- Detection, control and reporting of genotoxic impurities
- How to control genotoxic impurities in herbal medicinal products
- How to deal with residues of metal catalysts and reagents
- Extractables and leachables as a source of impurities
- Residual solvents as impurities in marketed products
- Impurities in biotechnology products
- Analytical methods used for detection of impurities
- How to report impurities in regulatory submissions

This event is designed to provide a comprehensive review of impurities analysis and characterisation in drug substances and drug products and their recording and reporting.

Background

Setting specifications for impurities are one of the most critical topics for a registration application. Impurities analysis in drug substances and drug products and their recording and reporting is quite often a challenge for the scientific experts in development and routine production. This challenge is even bigger when potential genotoxic impurities or residual metal catalysts have to be qualified and quantified. There is a specific EMA guideline on the specification limits for residues of metal catalysts or metal reagents which came into effect on 1 September 2008.

Target Audience

The conference addresses all personal involved in development of drug substances and drug products from scientific staff to laboratory heads. The conference also covers the needs of experts in regulatory submissions or assurance and those involved in chemical and pharmaceutical manufacture.

Programme

SESSION 1: FUNDAMENTALS IN IMPURITY TESTING

Impurity Analysis in Drug Substances

- Impurity profiling in synthetic drug substances
- Qualification of impurities
- Degradation studies
- Identification of chiral impurities
- Identification of polymorphic phases
- Identification of new impurities
- Impurities in starting materials and intermediates

Control of Impurities in Drug Products

- Pharmacopoeial tests and acceptance criteria
- Drug product specifications and parametric release
- Leachables and extractables
- Inorganic impurities
- Analytical test procedures – Validation aspects

SESSION 2: GENOTOXIC IMPURITIES

Strategies to detect, control and report genotoxic impurities

- What is genotoxicity?
- Regulatory background
- Risk assessment for potential genotoxic impurities and consequences thereof
- Case studies

Genotoxic Impurities in Herbal Medicinal Products

- Definition: What may be an “Impurity” in a herbal product?
- EC Guidelines applied to herbals
- Sources of genotoxic impurities in plant materials
- Analytical techniques to detect genotoxic impurities in herbal starting materials
- Impurities from transport and storage
- Impurities in imported Asian plant materials

Programme (cont'd)

SESSION 3: RESIDUAL SOLVENTS AND HEAVY METALS

Control of residues of metal catalysts and reagents

- Scope and applicability of the new CHMP guideline
- Setting concentration limits
- Risk assessment
- Relation with the European Pharmacopoeia tests
- Case studies

Residual Solvents in Marketed Products

- The ICH classification of residual solvents
- Limits of residual solvents
- Reporting levels
- Toxicological aspects
- What about new solvents not mentioned in the ICH guideline?
- ICH guidelines Q3C(R5) vs pharmacopoeial requirements

SESSION 4: IMPORTANT COMPLIANCE AND SUBMISSION ASPECTS RELATED TO IMPURITIES

Analytical Techniques for the Determination of Impurities

- Purity analysis by HPLC, impurity profile
- Residual solvents by GC
- Inorganic impurities (heavy metals, sulphated ash)
- For chiral compounds in addition: enantiomeric purity and proof of the absolute configuration

Practical Aspects of Methods Validation for Impurity Determination

- Important ICH and FDA guidelines
- Quantitation of impurities
- How to define an impurity profile (stress tests)
- Reference substances
- Validation of methods at various development stages
- Statistical approaches to method validation (LOD & LOQ)

Impurity Specifications through the Development Life Cycle

- Specifications in Phase I-III clinical studies
- Reporting limits
- Impurity specifications in MAA/NDA, examples

Reporting Impurities in Regulatory Submissions

- Presenting data on impurities in the CTD
- Requirements for an NDA
- Regulatory strategies for setting acceptance criteria for impurities
- Reasons for an application being rejected
- Documentation on impurities for clinical trials

SESSION 5: EXERCISES AND WORKSHOPS

Case study on a macrocyclic antibiotic; validation and quantification approaches
In this case study participants will consider approaches and implications for the development, validation and application of HPLC methodology for complex mixtures and the related impurity profiles. It is about the discussions of options rather than finding the 'right' approach.

Setting impurity specifications (based on batch analysis data)
This case study is about a drug substance going through a fast track development process. Participants will discuss development issues on the drug substance at each stage with respect to specific impurity profiles in different formulations.

Workshop Feedback and Discussions

Speakers

DR CHRISTOPHER BURGESS

Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

TREVOR COOMBER

Trevor Coomber is a Pharmaceutical Development Consultant with over 30 years experience in the industry. He spent six years as a Senior Project Team Leader and Analytical Science Manager in Pharmaceutical Development in Glaxo Wellcome. Prior to that, he was a Team Leader in the Analytical Development Laboratories in Wellcome.

PETER GASSMANN

Swiss Agency for Therapeutic Products, SWISSMEDIC, Bern, Switzerland.

DR GERD JILGE

In 1991 Gerd Jilge came to Boehringer Ingelheim working in product development where he was responsible for method development and validation for the application of analytical procedures. In 2000 Dr Jilge took a position in Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation for the submission of new and registered drug products. Since July 2007 he is working in Quality Management on method development for new drug substances.

DR GEROLF TITTEL

Dr Tittel is executive director of the private pharmaceutical institute LAT GmbH (QC and QA), the manufacturing site DRONANIA (specialized for herbals) and a development center for new herbal products (PHYTOVISIONS). He is responsible for contract research and contract manufacturing.

Social Event

On 23 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.

Special offer with Lufthansa – up to 20% discounted travel for all ECA Events Attendees

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. 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.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

Conference Exhibiton

The European Compliance Academy offers you 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,-. You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link „Conferences“ on the homepage.

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 guidances.

What Are the Benefits of ECA?

First benefit:
During the membership, you enjoy a EUR 200 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 a 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. 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 www.gmp-compliance.org

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.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme Module "Pharmaceutical Development Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Validation Manager
- ECA QA Manager
- ECA API Production Manager
- ECA Quality Control Manager
- ECA Technical Operations Manager
- ECA Computer Validation Manager
- ECA Regulatory Affairs Manager
- ECA Microbiological Laboratory Manager
- ECA Sterile Production Manager
- ECA Biotech Manager
- ECA Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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.gmp-compliance.org

Date
Wednesday, 23 May 2012, 9.30 h – 18.00 h
(Registration and coffee 9.00 – 9.30 h)
Thursday, 24 May 2012, 8.30 h – 17.30 h
Friday, 25 May 2012, 8.30 h – 12.00 h

Venue
Radisson BLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone: +45 33 96 50 00
Fax: +45 33 96 55 55

Fees
ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- (does not include ECA membership)
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 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 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 "ECA" to receive the specially negotiated rate (DKK 1,445.- per night, excl. breakfast) for the duration of your stay.

Reservation should be made directly with the hotel not later than 23 April 2012. Early reservation is recommended.

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

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
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 per e-mail at
becker@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at
+49-62 21 / 84 44 18, or per e-mail at
grimm@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

IMPURITIES
23-25 May 2012, Copenhagen, Denmark
☐ 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 HEIDELBERGwill 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)!