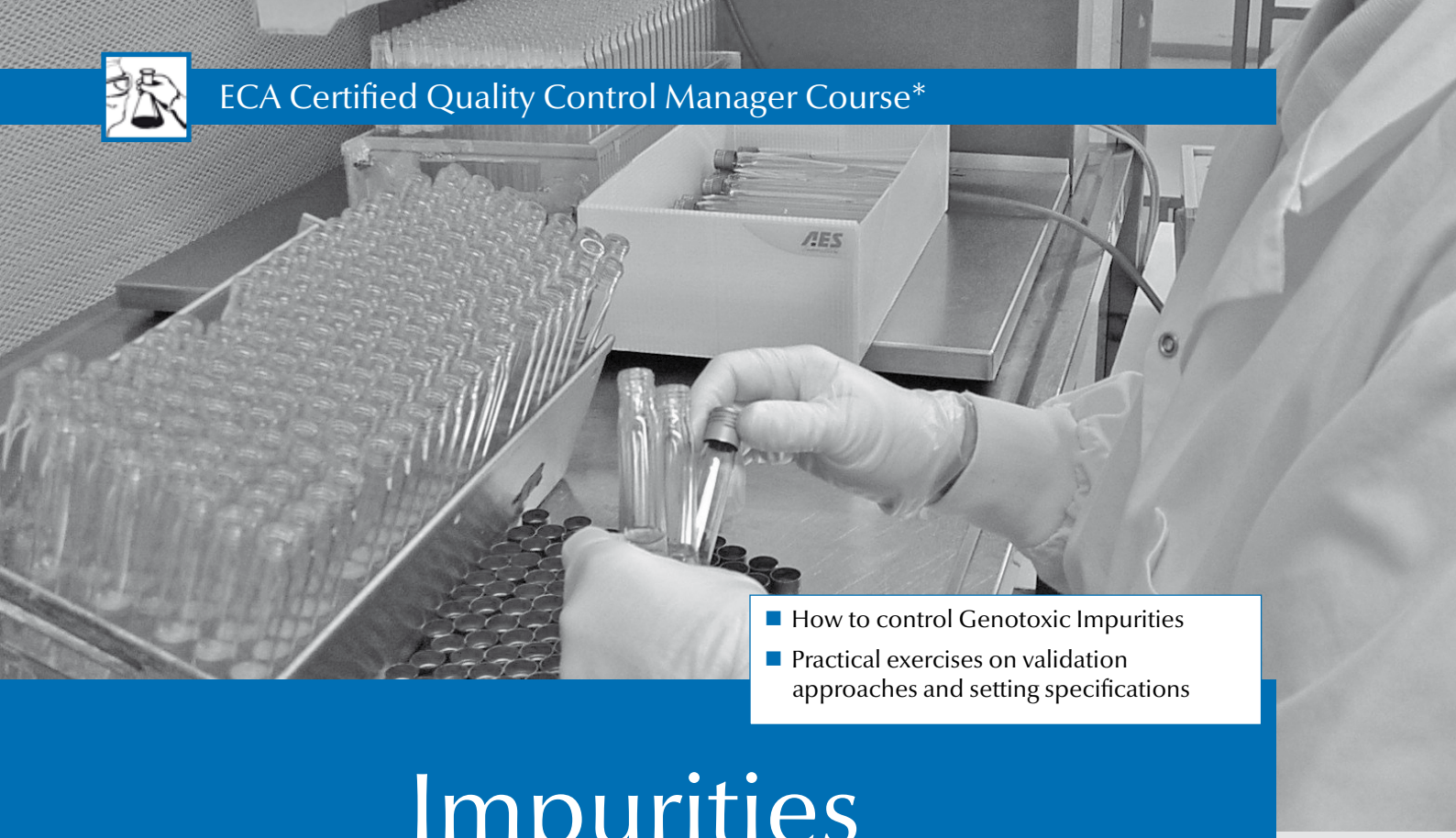

ECA Certified Quality Control Manager Course*

- How to control Genotoxic Impurities
- Practical exercises on validation approaches and setting specifications

Impurities

Detecting, Identifying, Quantifying, Specifying and Reporting

25 – 27 May 2011, Budapest, Hungary

SPEAKERS:

DR CHRISTOPHER BURGESS
Burgess Analytical Consultancy, United Kingdom

TREVOR COOMBER
Freelance Consultant, United Kingdom

GERD JILGE
Boehringer Ingelheim, Germany

REMCO STOL
Schering-Plough, The Netherlands

GEROLF TITTEL
LAT, Germany

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

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Impurities

25 – 27 May 2011, Budapest, Hungary

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.

Moderator

Dr Christopher Burgess

Programme 1st Day

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

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

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 2nd Day

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(R3) vs pharmacopoeial requirements

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

Practical Exercise

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.

Workshop Feedback and Discussions

Programme 3rd Day

Practical Exercise

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

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

Speakers

DR CHRISTOPHER BURGESS

Chris Burgess is an elected member of the USP Council of Experts on General Chapters, 2010-2015 and member of the Qualified Person Association Advisory Board. During his time in industry he worked mainly for Glaxo (now GSK) in Quality Control, Quality Assurance and Analytical R&D positions. He has recently been appointed as Visiting Professor at the Strathclyde Institute of Pharmacy and Biomedical Sciences (SIPBS) within the University of Strathclyde's Faculty of Science.'

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.

DR GERD JILGE

In 1991 Dr 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. Since 2000 Dr Jilge is working in the C Dept Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation, especially for the submission of new drug products.

DR REMCO STOL

Dr Remco Stol joined Organon, now part of Merck, in 2001 as a teamleader analytical chemistry. He has experience in early and late phase analytical development for APIs.

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 25 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.

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CONCEPT HEIDELBERG
P.O. Box 101764
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Reservation Form (Please complete in full)

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Impurities
25 – 27 May 2011, Budapest, Hungary

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If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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Easy Registration
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Germany

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e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Wednesday, 25 May 2011 2011, 10.00 h – 18.00 h
(Registration and coffee 9.30 – 10.00 h)
Thursday, 26 May 2011, 8.30 h – 17.30 h
Friday, 27 May 2011, 8.30 h – 12.30 h

Venue
Hilton Budapest WestEnd
Váci út 1-3
1062 Budapest, Hungary
Phone +36 1 288 5500
Fax +36 1 288 5588

Fees
ECA Members € 1,790.- per delegate plus VAT
Non-ECA Members € 1,990.- per delegate plus VAT
APIC Members € 1,890.- (does not include ECA membership)
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 has reserved a limited number of rooms in the conference hotel. Reservations should be made directly with the hotel. You will receive a POG link (Personalised Online Group Page) when you have registered for the event. There you also can modify/cancel your reservation until 15 April 2011 without any penalty. Please use this link for your room reservation or be sure to mention "VA 6991 ECA Event" to receive the specially negotiated rate for the duration of your stay.

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
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