ECA Certified Quality Control Manager Conference*

Workshops on
- Establishment and Use of Reference Material
- Measurements Uncertainty and Equipment Calibration
- Inspection of QC Labs

Reference Standards

Characterisation, Use and Maintenance of Analytical Reference Substances

16 – 17 November 2010, Berlin, Germany

Speakers

Dr Susanne Belz
Bonn, Germany

Ann-Kristin Bentsen
Novo Nordisk A/S, Denmark

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr L. Valentin Feyns
formerly US Pharmacopeia, USA

Jürgen Martin
Nycomed, Germany

Dr Christian Kulinna
Boehringer Ingelheim Pharma GmbH & Co KG, Germany

Dr Anne Munk Jespersen
Novo Nordisk A/S, Denmark

Dr Ulrich Rose
EDQM, France

Dr Gerolf Tittel
LAT GmbH, Germany

Programme

- Importance of Reference Standards and their use in pharmaceutical analysis
- Reference Substances of the European Pharmacopoeia: Establishment and Use
- Reference Materials for Herbal Medicinal Products
- Characterisation of Primary Reference Standards
- Measurement Uncertainty and Reference Materials
- Qualification of Protein Reference Materials
- USP Reference Standards
- Reference Standards used for Instrument Calibration and Qualification
- Audits and Inspections in Analytical Control Laboratories

ECA
EUROPEAN COMPLIANCE ACADEMY

* This conference is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager"

Reference Standards

16 – 17 November 2010, Berlin, Germany

Objectives

The objectives of this conference are to provide information on

- Establishment, maintenance, use and administration of primary and secondary reference standards to assure GMP-compliance
- What characterisation of a primary reference standard really entails
- The importance of measurement uncertainty
- The characterisation, establishment, maintenance and distribution of reference standards from the perspective of the European Pharmacopoeia (EP CRSs) and the United States Pharmacopoeia (USP RSs)
- Equipment qualification and calibration
- Reference Standards for herbals from the pharmacopoeial and industry perspective
- Reference materials for biotechnology derived products
- Identification of impurities in reference material via HPLC
- Audits and inspections in analytical quality control laboratories with respect to reference materials

The conference programme is rounded of by four workshops.

Background

The establishment, handling and use of reference standards is a key issue for analysts in every quality control laboratory in the pharmaceutical and API industry because the ability to demonstrate compliance of pharmaceutical products with the original licence approval conditions depends on the accuracy of the analytical results. Therefore the integrity of the reference material is pivotal to the consistency of all analytical determinations.

The application of reference standards is provided for in many monographs of the various pharmacopoeias (Ph. Eur., USP, BP, JP, etc) as well as in internal test procedures for finished products.

Target Group

This conference is designed for Analysts, Laboratory Managers, Laboratory Scientists, QC/QA Managers, Qualified Persons and will also be of significant interest to Regulatory Affairs Professionals and organisations providing a regulated contract laboratory service.

Moderator

Dr Christopher Burgess,
Burgess Analytical Consultancy, UK

Programme

Importance of Reference Standards and their Use in Pharmaceutical Analysis

- Terms, definition and classification of reference standards
- Primary and secondary standards
- What are reference standards used for?
- Aspects of pharmaceutical reference standards
- Standards throughout an API life cycle

SUSANNE BELZ
Federal Institute for Drugs and Medical Devices, Germany

Reference Substances of the European Pharmacopoeia: Establishment and Use

- Definition of primary and secondary standards
- Analytical techniques and methods used for the establishment
- CRSs for identification tests, impurities and degradation products as CRSs
- Assay standards
- Collaborative trials
- Correct use of Pharmacopoeial CRSs
- Reference Standards for Herbal Medicinal Products
  - New policy for "herbal monographs"
  - Active ingredients or marker substances as CRS
  - Herbal extracts as CRS
  - Establishment and content assignment

ULRICH ROSE, EDQM, France

Reference Materials for Herbal Medicinal Products

- Regulatory aspects
- How to write a monograph
- Primary – secondary – working standards
- Requirements for new natural substances
- International sources
- Impurities in herbal standards

GEROLF TITTEL
LAT GmbH, Germany

Characterisation of Primary Reference Standards

- Requirements on a Primary Reference Standard
- Synthesis
- Proof of the molecular structure by NMR-spectroscopy (^{1}H, ^{13}C), mass spectroscopy, IR- and UV-spectroscopy as well as elemental analysis
- Analysis of the solid state structure by single crystal X-ray diffraction, crystalline modification (polymorphism)
- Purity analysis by HPLC, impurity profile
- Residual solvents by GC
- Water content by Karl-Fischer titration
- Melting point and loss on drying by thermal analysis (DSC/TG)
- Inorganic impurities (heavy metals, sulphated ash)
- Potency
- For chiral compounds in addition: enantiomeric purity and proof of the absolute configuration

CHRISTIAN KULINNA
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Measurement Uncertainty and Reference Materials

- What is measurement uncertainty?
- Errors in analytical measurements
- Assigning measurement uncertainty to reference materials
- Error budgets in analytical procedures
- Why is the measurement uncertainty important in calibration?

CHRISTOPHER BURGESS
Burgess Analytical Consultancy, United Kingdom

Qualification of Protein Reference Materials

- Material used for Reference Material (RM)
- Considerations for a RM specification
- Additional characterisation – ID and Purity
- Homogeneity
- Assignment of Content and Potency
- How is change in RM batch handled?
- Stability

ANNE MUNK JESPERSEN
Novo Nordisk A/S, Denmark

Workshops

How to establish a primary protein reference material – case study
ANNE MUNK JESPERSEN, ANN-KRISTIN BENTSEN,
Novo Nordisk A/S, Denmark

Calculation of potencies and assigning of values to Primary and Secondary Reference Standards
CHRISTIAN KULINNA
Boehringer Ingelheim Pharma, Germany
ULRICH ROSE
EDQM, France

Measurement uncertainty and its application in calibration of equipment
CHRISTOPHER BURGESS
Burgess Analytical Consultancy, United Kingdom

USP Reference Standards

- Collaborative Evaluation
- House Standards
- Labeling
- Expiration

VALENTIN FEYNS
formerly US Pharmacopeia, USA

Reference Standards used for Instrument Calibration and Qualification

- 'Fitness for purpose' of analytical instruments & systems
- Types of standards used for Equipment Calibration and Qualification
- Traceability of standards
- Examples of Reference Standards and Materials including those for the calibration of
  - Analytical balances
  - pH meters
  - Spectrometers and spectrophotometric detectors
  - Chromatographs

CHRISTOPHER BURGESS
Burgess Analytical Consultancy, United Kingdom

Audits and Inspections in Analytical Control Laboratories

- Storage, labelling and expiry date of Reference Standards in the QC lab
- Documentation requirements
- Analytical testing and characterisation of Working (=Secondary) standards for assay, impurities and identity testing
- Handling and use of Reference Standards in analytical test procedures
- Content of the Reference Standard SOP
- Preparing for an inspection in QC labs
- Checklist for Reference Standard procedures
- Reference Material – Examples for non GMP compliance

JÜRGEN MARTIN
Nycomed, Germany

Workshop
Inspection in a Quality Control Laboratory focussing on reference materials

Speakers

DR SUSANNE BELZ
Laboratory manager in the Pharmacopoeia and Standard Registration Unit of the German Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany. Special experiences in analytical chemistry due to 20 years in research on different subjects in analytical chemistry and the current work in the pharmacopoeial laboratory. 3 years of experience in the assessment of quality dossiers. Responsible in the BfArM for all questions concerning reference substances. Recently, she was temporarily seconded to the European Commission, DG Research.

ANN-KRISTIN BENTSEN
Dr Ann-Kristin Bentsen studied Biochemistry at the University of Copenhagen and received her Master Degree in June 2004. In 2001 she joined Novo Nordisk as an Analytical Chemist working with analytical methods. Since 2002 she has worked as a Reference Material Coordinator for Novo Nordisk. She is responsible for establishment and maintenance of Reference Materials of proteins for new development projects within the portfolio of Novo Nordisk.

DR CHRISTOPHER BURGESS
Chartered Chemist with more than 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He is a "Qualified Person" and a qualified ISO Guide assessor and he has recently been appointed to the PDA (USA) Scientific Advisory Board on ‚OOS Task Force'.

DR L. VALENTIN FEYNS
Dr Feyns was a Scientific Fellow of the Monograph and Reference Standards Development Department at the United States Pharmacopeia in Rockville, Maryland. He was in charge of Scientific Outreach Programs, liaison with the USP Reference Standards Committee, and assisted in many of the scientific components of the USP Reference Standards Program. Dr Feyns retired in 2006.

JÜRGEN MARTIN
Responsible for reference standards, equipment qualification and calibration at Altana Pharma (former Byk Gulden), Singen. Additionally, Jürgen is operating his own software development enterprise.

DR ANNE MUNK JESPERSEN
Principal Scientist of Novo Nordisk A/S, Denmark. Reference Material Coordinator for hGH, glucagon and FVIIa in the Biopharmaceutical Support Unit, responsible of preparing the monographs and international reference material of all three products. She is also a member of the USP expert committee on Proteins and Polysaccharides.

DR CHRISTIAN KULINNA
Head of the Analytical Development Group, Drug Substances, at Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany. Responsible for the analytical characterization of drug substances (NCE's) within preclinical and clinical development.

DR ULRICH ROSE
Dr. Ulrich Rose is Scientific Officer at the European Directorate for the Quality of Medicines & Health Care (EDQM) in Strasbourg, France. He is involved in the establishment and monitoring of reference standards as well as in the elaboration and revision of monographs. More recently, he is particularly responsible for the establishment of herbal reference standards for monographs on herbal drugs and preparations. He is also the European Pharmacopoeia representative in the Q3D expert working group for metal impurities at ICH. Before joining the EDQM Dr. Rose was assistant professor and lecturer for pharmaceutical analysis at the Johannes Gutenberg University of Mainz. He is author of more than 30 publications.

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 in Berlin

On 16 November 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 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 guidances.

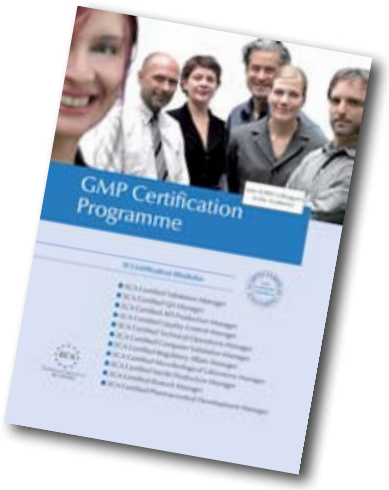
What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

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 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 **http://www.gmp-compliance.org**

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module "ECA Certified Quality Control Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:



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

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Reference Standards,
16 – 17 November 2010, Berlin, Germany

□ Mr. □ Ms.

Title, first name, surname

Company Department

IMPORTANT: Please indicate your company's VAT ID number! **P.O. 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)!

Easy Registration
Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
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e-mail:
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Internet:
www.gmp-compliance.org

Date
Tuesday, 16 November 2010, 09.00 h – 18.00 h
(Registration and Coffee 08.30 h – 09.00 h)
Wednesday, 17 November 2010, 8.30 h – 16.30 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone: +49 (0)30 2127 0
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Fees
Non-ECA Members: € 1,790.- per delegate + VAT
ECA-Members: € 1,611.- per delegate + VAT
EU GMP Inspectorates: € 895.- per delegate + VAT
APIC Members: € 1,700,- per delegate + VAT (does not include ECA Membership)
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. 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 "VA 6453 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 15 October 2010. 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
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