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

8 – 9 May 2012, Berlin, Germany

Speakers

Dr Susanne Belz
Berlin, Germany

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr L. Valentin Feyns
formerly US Pharmacopeia, USA

Dr Anne Munk Jespersen
Novo Nordisk A/S, Denmark

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

Jürgen Martin
Nycomed, Germany

Dr Elisabeth Gade Nielsen
Novo Nordisk A/S, Denmark

Dr Ulrich Rose
EDQM, France

Programme

- Importance of Reference Standards and their use in pharmaceutical analysis
- Reference Substances of the European Pharmacopoeia: Establishment and Use
- 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 education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager". Please find details at www.gmp-certification.eu

Reference Standards

8 – 9 May 2012, 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 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

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
ELISABETH GADE NIELSEN
Novo Nordisk A/S, Denmark

Workshops

How to establish a primary protein reference material – case study

ANNE MUNK JESPERSEN, ELISABETH GADE NIELSEN
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

From 2011 to 2011 Dr Belz was laboratory manager in the Pharmacopoeia and Standard Registration Unit of the German Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany. Prior to this, she worked in the department for pharmaceutical quality of BfArM. She has special experiences in analytical chemistry due to 20 years in research on different subjects in analytical chemistry and the work in the pharmacopoeial laboratory, as well as 3 years of experience in the assessment of quality dossiers. In addition, at BfArM she was responsible for all questions concerning reference substances. Since 2011 Dr. Belz works on the validation of alternative methods for animal testing in the Joint Research Centre of the European Commission in Ispra, Italy.

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'.

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.

Dr ELISABETH GADE NIELSEN
Reference Material Scientist at Global Metrology of Novo Nordisk A/S, Denmark. Before joining the Global Metrology Department she was Compliance Chemist and Lead Auditor in the CMC QA department and after that she worked as Reference Material Coordinator in the CMC Analytical Support of Novo Nordisk.

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.

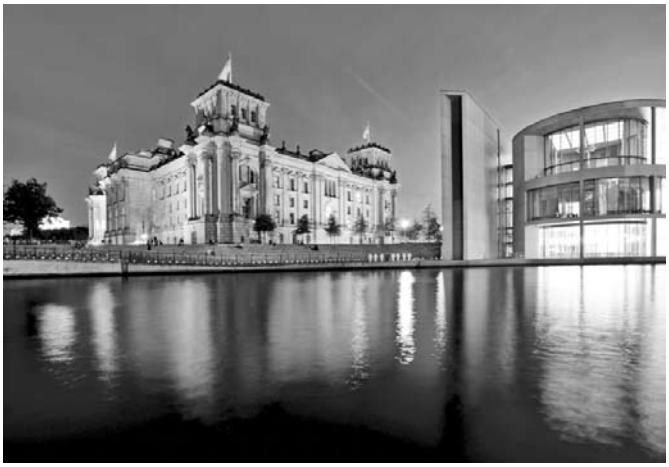
DR ANNE MUNK JESPERSEN
Principal Scientist of Novo Nordisk A/S, Denmark. Reference Material Coordinator for hGH, glucagon and FVIIa in the Biopharmaceutical Support Unit, responsible of preparing the monographs and international reference material of all three products. She is also a member of the USP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

DR ULRICH ROSE
Dr Rose is Scientific Officer at the European Directorate for the Quality of Medicines & Health Care (EDQM) in Strasbourg. He has a 20 years' experience in the management of the European Pharmacopoeia reference standards programme, but also participated in the elaboration and revision of monographs. Currently he is responsible for the management of the Mutual Joint Audit/Visit (MJA/MJV) – programme of the EDQM, where he co-ordinates the audits of the European Official Medicines Control Laboratories (OMCLs) according to ISO/IEC 17025. Dr Rose is also member of the "Analytical Quality Control Group" of ECA.

Social Event

On 8 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.



Easy Registration

Reservation Form:
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Germany

Reservation Form:
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e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Tuesday, 8 May 2012, 09.00 h – 18.00 h
(Registration and Coffee 08.30 h – 09.00 h)
Wednesday, 9 May 2012, 8.30 h – 16.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone: +49 (0)30 2127 0
Fax: +49 (0)30 2127 117

Fees

ECA-Members: € 1,590.– per delegate + VAT
APIC Members: € 1,690,- per delegate + VAT (does not include ECA Membership)
Non-ECA Members: € 1,790.– per delegate + VAT
EU GMP Inspectorates: € 895.– per delegate + 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. 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-Reference Standards" to receive the specially negotiated rate (single room € 125,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 7 March 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
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D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
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For questions regarding content:
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or per e-mail at becker@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager) at
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weidemaier@concept-heidelberg.de.

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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:

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- 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

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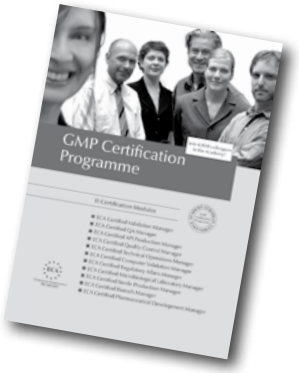

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Reservation Form (Please complete in full)

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Reference Standards, 8 – 9 May 2012, Berlin, Germany

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