ECA
European Compliance Academy

- Update on New Monographs
- Dealing with Divergent Compendial Methods

Compliance Update: EP, USP, and JP

Speakers:

Dr Christopher Burgess
Burgess Analytical Consultancy, UK

Dr Bob McDowall
McDowall Consulting, UK

Dr Oliver Grosche
Novartis Pharma AG, Switzerland

Dr Bernd Renger
European QP Association, Germany

21 – 22 June 2012, Prague, Czech Republic

Highlights

- Structure of Monographs
- Integrating Analytical Instrument Qualification (AIQ) and Computerised System Validation (CSV): Extension of USP <1058>
- Elemental Impurities according to Proposed USP Chapters and EP
- Revision of USP General Chapters on
  - Transfer <1224>
  - Validation <1225>
  - Verification <1226>
- New USP Chapters for Spectroscopic Methods
- Dissolution Testing – USP Chapter <711> versus FDA Mechanical Calibration Approaches for Apparatus I and II
- Analytical Testing According to JP
- How to Deal with Divergent Compendial Method Requirements

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

Compliance Update: EP, USP, and JP

21 – 22 June 2012, Prague, Czech Republic

Objectives

This Conference will inform you about the latest developments of some general chapters of the most significant pharmacopoeias (EP, USP, and JP). Topics to be covered are:

- Analytical instrument qualification (AIQ),
- Elemental impurities,
- Method validation, verification, and transfer,
- Spectroscopic methods, and
- Dissolution testing

One key focus of the conference is the handling of varying specifications in the different pharmacopoeias for identical APIs and excipients used for finished drug products dedicated for the markets in Europe, US, and Japan. Must different tests be conducted according to EP, USP, and JP, respectively? Can a pharmacopoeial test be replaced by an alternative test method?

Background

Pharmacopoeias are defining normative standards to be followed by the pharmaceutical industry, specifically by laying down monographs for APIs and excipients and corresponding general chapters for specific test procedures like Chromatography (HPLC, etc.) or Dissolution Testing, etc.. In addition, pharmacopoeias are defining many particular requirements for specific dosage forms as tablets or capsules, etc..

Actually some of the most important general chapters are being revised and updated or some texts will be established as completely new chapters. It's the aim of this conference to provide an overview on the most important new developments in pharmacopoeial analytical testing.

Harmonisation is another big issue. Harmonisation was a request of the pharmaceutical industry, struggling with the unnecessary burden of redundant testing as companies were becoming increasingly operating multinational.

Under the roof of the ICH, the Pharmacopoeial Discussion Group (PDG) and the ICH Q4B Working Group have been dealing for years with the harmonisation of the requirements laid down in the pharmacopoeias of the three ICH regions. The PDG was founded in 1990 comprising representatives from EDQM, MHLW (Japan) and the USP. Its goal is to harmonise monographs for selected excipients and for a number of general chapters of the pharmacopoeias. The ICH Q4B Expert Working Group (EWG) was established in 2003 and aimed at evaluating all test methods included in ICH Guideline Q6A on Specifications. Test procedures are evaluated whether they are interchangeable, which is defined as follows: "Where such status is indicated, any of the official texts from JP, EP, or USP can be substituted one for the other (appropriately referenced) in the ICH regions for purposes of the pharmaceutical registration / approval process".

The primary benefit of harmonisation for industry is the elimination of redundant testing, not only in the registration / approval process but also in the testing and sampling of APIs and excipients in routine Quality Control.

Target Audience

This Conference is directed at all those employees from quality control units in the pharmaceutical industry (including QP, head of QC and laboratory manager), responsible for sampling, testing and release of APIs and excipients. The conference is also of interest for personnel from quality assurance and regulatory affairs.

Programme

Structure of Monographs; Similarities and Differences; USP & EP

- General Notices
- Extent and content
- Methodological control
- Use of reference standards and measurement uncertainty
- System Suitability requirements
- Linkages to General Chapters

Dr Christopher Burgess, Burgess Analytical Consultancy, UK

An Integrated Approach to Analytical Instruments Qualification and Computerised System Validation: Extension of USP <1058>

- Current problems with USP <1058>
- Analytical Instrument Qualification approaches in EP and JP
- Differences between GAMP and <1058>
- New USP <1058> stimulus to the revision process 2012
- Comparison with the new GAMP Laboratory Systems Guide

Dr Bob McDowall, McDowall Consulting, UK

Elemental Impurities according to proposed USP General Chapters <232> / <233> and Ph. Eur. 5.20 and 2.4.20

- Why is a change required?
- Current regulations and limits
- Structure of newly proposed chapters
- Methods of analysis
- Impact on materials and processes (API, Excipients, Drug Product)
- Strategies to prepare for new requirements
- Recent developments with ICH on elemental impurities

Dr Oliver Grosche, Novartis Pharma AG, Switzerland

Assurance and Transfer of Analytical Procedures – Revision of USP General Chapters; <1224> Transfer of Analytical Procedures; <1225> Validation of Analytical Procedures and <1226> Verification of Compendial Procedures

- Climate for change
  - Obsolescence of ICH Q2(R2)
  - Challenges of technology transfer
  - Transition from ICH to ISO based measurement uncertainties
  - USP Expert Panel 2011-2012 for the revision of USP General Chapters <1224>, <1225> and <1226>
- Methodologies for method transfer
  - Within companies
  - Between companies
  - Pharmacopoeial methods
- Current status of initiatives

Dr Christopher Burgess, Burgess Analytical Consultancy, UK

New USP Chapters for Spectroscopic Methods

- Modernisation of the USP
  - Legal requirement or Best Practice guidance?
  - Unique nature of the USP amongst the pharmacopoeias
  - USP and the FDA
  - Harmonisation issues
  - Revision of General Chapter <1058> on Analytical Instrument Qualification
- Approaches of the European and Japanese Pharmacopoeias on spectroscopic requirements
- Issues with legacy General Chapters <851> Spectrophotometry and Light-Scattering and <197> Spectrophotometric Identification Tests
- USP Proposals
  - Atomic Absorption Spectroscopy
  - Fluorescence Spectroscopy
  - Mid InfraRed Spectroscopy
  - Nuclear Magnetic Resonance Spectroscopy
  - Near Infrared Spectroscopy
  - Raman Spectroscopy
  - Ultraviolet-Visible Spectroscopy

Dr Christopher Burgess, Burgess Analytical Consultancy, UK

Programme, cont'd

Dissolution Testing: USP Chapter <711> versus FDA Mechanical Calibration Approaches for Apparatus I & II

- USP requirements of USP <711>
- Harmonisation and differences of <711> with EP and JP requirements for dissolution
- FDA approaches to dissolution bath calibration
- Holistic versus modular qualification approaches applied to dissolution testing
- Changes to USP Calibrator tablets: availability and calculations

Dr Bob McDowall, McDowall Consulting, UK

Analytical Testing According to JP

- Specifics in Method descriptions
- System Suitability Testing according JP
- Specific requirements for APIs
- Analytical validation for submission to JP (Intermediate Precision)
- Dissolution testing specifics
- Survival strategies when the English translation of e.g. JP16 is not yet available

Dr Oliver Grosche, Novartis Pharma AG, Switzerland

Multicompendical Testing – PQRI Survey

Dr Oliver Grosche, Novartis Pharma AG, Switzerland

How to Deal with Divergent Compendial Method Requirements (EP, USP, JP)

- ICH QB4 "Harmonisation of pharmacopoeial procedures" and its Annexes
- CDER's MAPP 5310.7 "Acceptability of Standards from Alternative Compendia (BP/EP/JP)"
- Strategies to avoid redundant testing in case of missing harmonization
- Alternative test procedures to existing compendial test methods

Dr Bernd Renger, European QP Association, Germany

WORKSHOP
Multicompendial and Alternative Testing
Based on real case studies, the attendees will develop alternative strategies in case of non-harmonised compendial requirements or if the test procedure is deviating from the method as described in the pharmacopoeia.
Dr Bernd Renger, European QP Association

OOS Forum 2012, 19-20 June 2012, Prague, Czech Republic
On 19-20 June 2012, i.e. on Tuesday and Wednesday of the same week, the OOS Forum will take place in the same hotel in Prague. ECA's OOS SOP will be presented at this OOS Forum and members of ECA's OOS Review Team will discuss alternative approaches and comments from other pharmaceutical companies (Bluepharma, GSK, Roche, and Novo Nordisk).

Further topics are:

- OOS – US/FDA Expectations
- OOS – Expectations of a European GMP Inspector
- Fundamentals of Analytical Variability
- Terms Used in OOS Investigations
- Isolation and Evaluation of Outliers: Which is the right Number of Retests?
- Out-of-Trend Results
- Pharmacopoeial Compliance
- OOS in R&D Laboratories
- OOS in Biologics
- OOS in Microbiology

Further information about this conference can be found at www.oos-forum.org. Register simultaneously for both courses and receive a 350 € discount (not valid for EU GMP Inspectorates).

Speakers

Dr Christopher Burgess,
Burgess Analytical Consultancy Limited, Barnard Castle, UK
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 Oliver Grosche
Novartis Pharma AG, Basel, Switzerland
Dr Oliver Grosche is analytical expert by training and leading the Pharmacopeia and GxP intelligence process at Novartis Pharma Global Technical Operations, Basel, Switzerland. After being involved in the worldwide registration of two innovative drug substances, he moved 2006 to Japan for an international assignment. His main work was to develop on both, the Swiss and the Japanese side a common understanding of analytical processes and requirements required for a Japan specific submission. Besides his continuing role in supporting "Japan-Specifics", he is leading the implementation strategy on elemental impurities in his department.

Dr Bob McDowall
McDowall Consulting, Bromley, Kent, UK
Analytical chemist with over 35 years experience including 18 years working in the pharmaceutical industry as a consultant. He is Principal of McDowall Consulting, UK. Bob is an ISO 17025 assessor and he has been involved with the validation of computerised systems for over 20 years and is the author of a book on the validation of chromatography data systems. Bob is also the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several Journals.

Dr Bernd Renger
Chairman of the European QP Association, Germany
Dr Bernd Renger is a member of the ECA Advisory Board and Chairman of the European QP Association. Since 2011, is running his own consultancy business. Before that he was Director of Quality Control at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several quality positions at Mundipharma, Altana Pharma and Baxter.

Social Event

On 21 June 2012, 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:
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
Thursday, 21 June 2012, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Friday, 22 June 2012, 08.30 - 14.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069, Praha 4, Czech Republic
Phone +420 261 191 111
Fax +420 261 225 011

Conference fees
ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- 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.

Would you like to safe money?
If you register for ECA's OOS Forum from 19-20 June 2012 at the same time, you will receive a 350 € discount. This is not valid for EU GMP Inspectorates.

Accommodation
CONCEPT HEIDELBERG 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 conference.

Please use this form for your room reservation or be sure to mention "XCON200612" to receive the specially negotiated rate (single room € 137,50 per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 23 May 2012. Early reservation is recommended.

Registration
Via 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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P.O. Box 10 17 64
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69007 Heidelberg
Germany

Registration form (please complete in full)

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☐ Yes, I also want to participate in ECA's OOS Forum on 19 - 20 June 2012, Prague, Czech Republic

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

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General Terms of Business

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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**