Participate in 4 Workshops!

Foto: BÜCHI

Analytical Instrument Qualification

Practical Approaches for USP General Chapter <1058> Compliance in the QC Laboratory

19 - 21 May 2014, Berlin, Germany

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK

Judith Kernbichler
Baxter Bioscience, Austria

Roland Miksche
Baxter Bioscience, Austria

LEARNING OBJECTIVES:

- Regulatory Aspects of Analytical Instrument Qualification
- USP General Chapter <1058> - Analytical Instrument Qualification
- Risk Assessment in Analytical Laboratories
- Calibration Management
- Balances and Weighing Processes
- Practical Examples of Analytical Instrument Qualification and Calibration:
  - Spectroscopic Instruments and Detectors (UV/VIS, IR, NIR, NMR, etc.)
  - pH Measuring Instruments
  - HPLC / GC
  - ELISA
  - Plate Readers
  - Thermometers and Hygrometers
- Computer Validation in Analytical Laboratories
- Validation of Excel® Spreadsheets

ECA ACADEMY

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

Analytical Instrument Qualification

19 - 21 May 2014, Berlin, Germany

Learning Goals

Calibration and qualification of equipment are key requirements in GMP guidelines (EU GMP Guide, Annex 15 to EU GMP Guide, and FDA's Code of Federal Regulations, 21 CFR Part 211). These requirements also apply to instruments and systems in analytical laboratories of the pharmaceutical industry. Besides calibration and qualification, the validation of computerised systems is another key issue. The software components associated with the instruments and systems must be shown to be fit for their intended purpose. Computer validation requirements and guidances for the pharmaceutical industry are laid down, amongst others, by the EU (Annex 11 to EU GMP Guide, the PIC/S (Good Practices for Computerised Systems in Regulated "GXP" Environments"), GAMP® (Good Automated Manufacturing Practice), and FDA's Part 11.

In 2006 the United States Pharmacopoeia (USP) has published a new General Chapter <1058>, Analytical Instrument Qualification, which has been adopted in USP 30 in 2008. This General Chapter <1058> is currently under revision and there will be a short presentation on possible changes which will align with the new USP Validation and Verification Expert Panel on Analytical Procedures revising <1224>, <1225> & <1226> concepts and the GAMP® Good Practice Guide for Laboratory Computerized Systems, 2nd Edition, 2012.

The objective of this course is to provide the participants with an overview of the regulatory requirements on the qualification of analytical equipment and the software validation of computerised systems and to give practical advice on successful approaches to calibration, qualification, validation, and routine monitoring of instrumentation and systems. **Key requirements of the important USP General Chapter <1058> will be presented and discussed.**

The course will cover the following instruments and systems amongst others:

- Spectrophotometers (UV/VIS, NIR and IR)
- Balances and Masses
- pH
- Plate Readers / ELISA
- HPLC and GC
- Chromatographic Data Systems
- Excel® Spreadsheets

Interactive **workshops** will allow the participants to discuss key areas of interest and to exchange practical experiences.

Target Group

This GMP Education Course will be of practical value to scientists and engineers in analytical laboratories and contract laboratories in an FDA-/GMP-regulated environment who are responsible for the calibration and qualification of their laboratory equipment and for the validation of the computerised systems used in their laboratories.

Programme

Regulatory Aspects of Analytical Instrument Qualification

- Legislation
  - Europe: EU GMP Guide - Annex 15
  - US: CFR, USP
  - International: PIC/S document PI 006-2
  - National: German ZLG quality manual
- Interpretation documents, FDA expectations
- Qualification steps / Equipment life cycle

JUDITH KERNBICHLER
Baxter Bioscience, Austria

USP General Chapter <1058> - Analytical Instrument Qualification

- Key recommendations of this USP General Chapter
- Qualification steps: which activities should be performed in each phase?
- Roles and responsibilities for the user, Quality Assurance and for the manufacturer
- Impact on Laboratory Operations

JUDITH KERNBICHLER
Baxter Bioscience, Austria

Proposed Changes of USP General Chapter <1058>

- In process revision of <1058>
- Need for harmonization of <1058> with the concepts contained in the GAMP® Good Practice Guide; A Risk-Based approach to GxP Compliant Laboratory Computerized Systems, 2nd Edition, 2012
- Compatibility of <1058> with USP Validation and Verification Expert Panel on Analytical Procedures proposals revising General Chapters <1224>, <1225> & <1226>

Dr CHRISTOPHER BURGESS
Burgess Analytical Consultancy Ltd., UK

General Aspects of Calibration

- Basic concepts, definition, terminology
- Overview: Laws, regulations, standards and guidelines
- Uncertainty & traceability in analytical measurement
- Calibration issues in audits and inspection
- Practical examples of common out of tolerance results in calibration
- Practical approaches for remedial actions

Dr CHRISTOPHER BURGESS
Burgess Analytical Consultancy, UK

WORKSHOP I

Topic: Apparatus & Instruments List Case Study / Risk Categorisation According to USP <1058>
MODERATOR: Dr Christopher Burgess

Risk Assessment in Analytical Laboratories

- Scarring examples
- Advantages of minimizing risk
- Definition and regulation (EU GMP Part 3 - Risk Management, etc.)
- Approach, applicability, documentation, approvals
- FMEA (Failure Mode and Effect Analysis)
- HACCP (Hazard Analysis and Critical Control Points)
- ISHIKAWA DIAGRAM (Fishbone)
- FTA (Fault Tree Analysis)
- Risk assessment of changes

ROLAND MIKSCHE
Baxter Bioscience, Austria

WORKSHOP II

Topic: Qualification / Risk Analysis of pH Measuring Instruments
MODERATOR: Roland Miksche

Calibration Management

- Documentation
  - Inventory / instrument master data
  - Calibration scheduling and tracking
  - Instrument performance history
- Calibration standards
- Calibration interval adjustment
- Out of tolerance evaluation
- Supporting calibration management software

JUDITH KERNBICHLER
Baxter Bioscience, Austria

Qualification of Spectroscopic Instruments and Detectors

- Technical approaches for the qualification and calibration of spectroscopic instruments
- Traceability of standards
- Qualification and calibration aspects for
  - UV-Visible
  - NIR
  - IR
  - Raman
  - Polarimetry
  - Circular Dichroism
  - NMR

Dr CHRISTOPHER BURGESS
Burgess Analytical Consultancy, UK

Qualification of GC Instruments

- Warning Letters (483) and Findings
- Technical Overview, Applications
- From Vendor to Decommissioning: AIQ-Lifecycle
- System Suitability Test
- Periodic Review (Checklist)

ROLAND MIKSCHE
Baxter Bioscience, Austria

Balances and Weighing Processes

- Fundamentals of weighing
- Best practices in weighing; USP <1251>
- USP <41> and minimum weight
- Traceability of mass
- Performance qualification of balances

Dr CHRISTOPHER BURGESS
Burgess Analytical Consultancy Ltd., UK

WORKSHOP III

Topic: Balances
MODERATOR: Dr Christopher Burgess

Case Study: ELISA Qualification

JUDITH KERNBICHLER
Baxter Bioscience, Austria

Plate Readers

- Design issues of multichannel plate readers
- Qualifications as fitness for purpose
- Photometric & Wavelength accuracy and precision
- Temperature control
- Holistic Testing

Dr CHRISTOPHER BURGESS
Burgess Analytical Consultancy Ltd., UK

Assurance of Controlled Temperature and Humidity

- Thermometers and thermometry
- Hygrometers and hygrometry
- Qualification approaches to
  - Thermostatic controllers
  - Water baths & HPLC column temperature environments
  - Ovens & muffle furnaces
  - Refrigerators & freezers
  - Climatic storage rooms and incubators

Dr CHRISTOPHER BURGESS
Burgess Analytical Consultancy Ltd., UK

General Aspects of Computer Validation in Analytical Laboratories

- PIC/S Guidance Good Practices for Computerised Systems in Regulated "GXP" Environments
- New EU GMP Annex 11 Computerised Systems
- Requirements of 21 CFR Part 11
- Life cycle concept
- Integration of equipment qualification and computer validation
- Retrospective validation

ROLAND MIKSCHE
Baxter Bioscience, Austria

HPLC / Chromatography Data Systems – Integrated Qualification and Validation

- Master Validation Plan (MVP)
- Assessments (Risk to Quality, 21 CFR Part 11)
- User Requirement Specification (URS)
- Function- and Design Specification (FS/DS)
- Risk Analysis (RA)
- Validation Protocol (VP)
- Test Cases (Deviations, Incidents, Changes)
- Final Report (FR)
- Standard Operation Procedures (SOP)
- Forms (User Access, Monitoring, Updates...)
- Service Contracts, Helpdesk, Logbook

ROLAND MIKSCHE
Baxter Bioscience, Austria

Validation of Excel® Spreadsheets

- Areas of Usage
- Known Errors and Findings
- Categorisation according to GAMP®
- Lifecycle Phases and Documentation:
  - Requirements Phase
  - Definition, Build Phase
  - Testing Phase
  - Release
  - Changes, Decommissioning
- Literature (Regulations, Guidances)

ROLAND MIKSCHE
Baxter Bioscience, Austria

WORKSHOP IV

Topic: Validation of Excel Spreadsheets (Categorisation, responsibilities, required documents, contents of documents, testing, versioning, data handling)
MODERATOR: Roland Miksche

Speakers

Dr CHRISTOPHER BURGESS

Burgess Analytical Consultancy, Barnard Castle, UK

Dr Burgess is a Chartered Chemist and has more than 39 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.

JUDITH KERNBICHLER

Baxter Bioscience, Orth an der Donau, Austria

Judith Kernbichler did her master in technical Chemistry at the Technical University of Graz, Austria in 1997 and has since then worked in the quality departments of different companies. Since 2002 she has been working for Baxter Bioscience in Vienna (A), Neuchatel (CH) and Orth an der Donau (A). During this period she could gain a lot of experience in method validation, equipment qualification and other GMP-related topics that are important for QC laboratories.

ROLAND MIKSCHE

Baxter Bioscience, Vienna, Austria

Roland Miksche is member of the Quality Assurance Department at Baxter BioScience Vienna, Austria. He has been within Baxter since 2001 when he was responsible for developing requirements for computerized systems validation including excel spreadsheets. He acts as Quality System Representative in Global IT-Projects. He made his final exam in biochemistry in Vienna and worked as an analyst in accredited laboratories and as a sales expert for scientific equipment.

Social Event

At the evening of the first course day all participants and speakers are invited to a guided sight-seeing tour of the city of Berlin, followed by a dinner, where the topics of the course can be further discussed in a relaxed atmosphere.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification 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.

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to 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. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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.

Lufthansa is Mobility Partner for all ECA Events

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!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Analytical Instrument Qualification
19 - 21 May 2014, Berlin, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **PO Number if applicable**

Street/P.O. Box

City Zip Code Country

Phone/Fax E-Mail (please fill in)

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

D-69007 Heidelberg
GERMANY

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)! (as of January 2012)

Date

Monday, 19 May 2014, 9.00 h - 18.00 h
(Registration and coffee 08.30 h - 9.00 h)
Tuesday, 20 May 2014, 08.30 h - 18.00 h
Wednesday, 21 May 2014, 08.30 h - 16.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7-799

Fees

ECA Members € 1,790,- per delegate plus VAT
APIC Members € 1,890,- per delegate plus VAT (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 all three 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 with all further information when you have registered for the event. Reservation should be made directly with the hotel. 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
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Günter Brendelberger (Operations Director) at +49-(0)62 21 84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.: Ms Marion Weidemaier (Organisation Manager) at +49-(0)62 21 / 84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.