ECA Certified Quality Control Manager Course*

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Lab Equipment Qualification

Calibration and Qualification in Analytical Laboratories according to the New USP General Chapter <1058> „Analytical Instrument Qualification“

4 - 6 October 2010, Budapest, Hungary

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK

Judith Kernbichler
Baxter Bioscience, Switzerland

Roland Miksche
Baxter Bioscience, Austria

LEARNING OBJECTIVES:

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

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

Lab Equipment Qualification

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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 equipment 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 and Draft Revision of Annex 11), 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 the first supplement of USP 30 in 2008.

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 new 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 Lab Equipment 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, Switzerland

USP General Chapter <1058> - Analytical Instrument Qualification

- Key recommendations of the new 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, Switzerland

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: Equipment 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 (New EU GMP Annex 20 Quality 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

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, Switzerland

WORKSHOP II

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

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 Equipment

- 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, Switzerland

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

Calibration and Qualification in

FDA Warning Letters

- *Inadequate laboratory equipment calibration program: failure to have written procedures describing specific calibration instructions and limits .*
- *Failure to conform to the USP section «41» for weight and balance determination. The inspection revealed that erroneous values are being used to perform the minimum weight studies.*
- *No certification to a recognised standard for the weights set used for checking the balance.*
- *The calibration procedure for HPLC systems is inadequate in that it did not include integrator and detector's linearity, injector's reproducibility, and accuracy of temperature settings for column heater and detector.*
- *There are no predetermined acceptance criteria for the HPLC auto sampler calibration.*
- *The calibration procedure for GC systems is inadequate as it did not address calibration of flow rates, accuracy of temperature settings for column and injection port temperature, injector's reproducibility, and detector's linearity.*
- *Temperature and flowrate calibration checks were not performed on GC headspace unit.*
- *Procedures for UV/VIS Spectrophotometer only assesses linearity using alkaline potassium chromate solution at one wavelength when analytical tests are performed at various wavelengths. The procedures does not include functional tests such as wavelength accuracy, photometric accuracy, and reproducibility within ranges of intended use for the instrument.*
- *The calibration for dissolution apparatus does not evaluate parameters such as shaft wobble and shaft centering.*
- *Calibration raw data and results obtained for the performance qualification of analytical instruments is not being checked for accuracy and completeness by a second analyst or laboratory supervisor.*

General Aspects of Computer Validation in Analytical Laboratories

- PIC/S Guidance Good Practices for Computerised Systems in Regulated "GXP" Environments
- New EU GMP Draft 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 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 has over 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He has MSc and PhD degrees from Loughborough University in Analytical Chemistry. Dr. Burgess is a Qualified Person under the provisions of Directives 75/319/EEC and 81/851/EEC, a Chartered European Chemist and is a qualified ISO Guide 17025 assessor. Dr. Burgess has published over 60 papers and books in analytical science. He is also a member of the European QP Association Advisory Board.

JUDITH KERNBICHLER

Baxter Bioscience, Neuchatel, Switzerland
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) and Neuchatel (CH). 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 Budapest, 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.

The Three Most Important Guidelines and Comparison Matrix in One Booklet

The European Compliance Academy (ECA) has developed a Good Practice Guide „FDA cGMP, EU / PIC/S GMP and ISO 9001 Matrix for a pharmaceutical Quality System".
This Roadmap includes the full-text version of the three Guidelines:

- FDA's cGMP Guide (21 CFR 210/211)
- PIC/S GMP Guide incl. Annex 18 / ICH Q7A (identical with EU GMP Guide)
- ISO 9001 on Quality Management Systems

The three Guidelines will be supplemented by a GMP/ISO Matrix that compares the requirements of all three Guidelines. The booklet contains 20 pages of the GMP Matrix and 390 for the three Guidelines.
You can purchase the booklet that is printed in an easy-to-use format on the Internet at www.gmp-compliance.org. If you do so, you will be granted the ECA Members price of 99.- € (plus VAT and shipping costs). The regular price is 149.- € (plus VAT and shipping costs).

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 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**

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.

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

Lab Equipment Qualification
4 - 6 October 2010, Budapest, Hungary

☐ 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

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)!

Date

Monday, 4 October 2010, 9.00 h - 18.00 h
(Registration and coffee 08.30 h - 9.00 h)
Tuesday, 5 October 2010, 08.30 h - 18.00 h
Wednesday, 6 October 2010, 08.30 h - 16.00 h

Venue

Hilton Budapest WestEnd
Váci út 1-3
1062 Budapest
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Tel.: +36 1 288 5500
Fax : +36 1 288 5588

Fees

Non-ECA Members € 1,990,- per delegate plus VAT
ECA Members € 1,791,- per delegate plus VAT
APIC Members € 1,891,- per delegate plus VAT (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 all three days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. Please make your reservation via the Personalised Online Group Page POG www.budapest-westend.hilton.com/ECA041010 where you also can modify/cancel your reservation until 4 September 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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Dr Günter Brendelberger (Operations Director) at +49-62 21 84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.: Ms Marion Grimm (Organisation Manager) at +49-62 21 / 84 44 18, or per e-mail at grimm@concept-heidelberg.de.