ECA Academy
Your GMP/GDP Information Source

Analytical Instrument Qualification

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

Image: BÜCHI

Participate in 4 Workshops!

27 February – 1 March 2019, Budapest, Hungary

SPEAKERS:

Jörg Kastenschmidt
Merck, Germany

Philip Lienbacher
Shire, Austria

Roland Miksche
MiRo Consulting Vienna, 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
  - RAMAN / NIR / FT-IR
  - Thermometers and Hygrometers
- Computer Validation in Analytical Laboratories
- Validation of Excel® Spreadsheets
- Data Integrity Challenges in Calibration and Qualification

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

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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 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.

The United States Pharmacopoeia (USP) has adopted the General Chapter <1058>, Analytical Instrument Qualification, in 2008. This General Chapter <1058> has been updated in 2017.

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:

- UV/VIS Spectrophotometers,, Disintegration and Dissolution)
- Balances and Masses
- pH
- RAMAN / NIR / FT-IR
- 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

- Overview about legislations including
  - Europe: EU GMP Guide - Annex 15
  - US: CFR, USP
  - National: German ZLG quality manual
- Other relevant documents (Interpretation documents) and authority expectations
- Overview about Qualification steps
- Equipment life cycle

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/vendor
- Software validation, Change Control & Documentation
- Instrument categories

General Aspects of Calibration

- Overview: regulatory aspects / requirements
- Definitions / terminology
- Concepts and documentation
- Handling OOC (Out of Calibration)

WORKSHOP I

Topic: Apparatus & Instruments List Case Study / Risk Categorisation According to USP <1058>
MODERATOR: Joerg Kastenschmidt

Risk Assessment in Analytical Laboratories

- Scaring examples
- Advantages of minimizing risk
- Definition and regulation (EU GMP Part 3 - 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

WORKSHOP II

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

Calibration Management
- Parts of a calibration management system
  - Procedure(s)
  - Documentation
  - Calibration standards
  - Calibration management software
- Calibration interval adjustment
- OOC/OOT evaluation
- What can go wrong and how to avoid it

Data Integrity Challenges in Calibration and Qualification
- Relevant Guidelines
- Documentation- & Data-management-Systems in the Pharma/Device industry
- Achieving data integrity: Creating a culture of quality around document- and data management
- What can go wrong and how to avoid it!

Qualification of Specific Instruments and Systems
- Requirements according to USP
- Traceability of standards
- Practical approaches to qualification and calibration of
  - UV-Visible
  - Dissolution
  - Disintegration
  - Osmometer
  - Particulate Matter
  - Turbidity
  - Dishwasher

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

Balances and Weighing Processes
- Weighing basics
- Environmental influences on weighing
- Practical aspect on weighing
- Requirements acc. to USP <41> and <1251>
- Qualification and calibration of balances
- Weights (OIML R111-1)

WORKSHOP III
Topic: Balances
MODERATOR: Joerg Kastenschmidt

Qualification of RAMAN / NIR / FT-IR
- Quick overview RAMAN / NIR / FT-IR & benefits
- Qualification: What are the specifics?
- Potential difficulties

Volumetric Apparatus (Pipets, Dispensers, etc.)
- Selection of suitable apparatuses
- Qualification / calibration
- Volumetric laboratory glassware

Assurance of Controlled Temperature and Humidity
- Thermometers and thermometry
- Hygrometers and hygrometry
- Qualification approaches to
  - Refrigerators and freezers
  - Climatic storage rooms and incubators
  - Ovens & muffle furnaces
  - Water baths

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

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

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)

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

Speakers

JOERG KASTENSCHMIDT
Merck, Darmstadt, Germany
Jörg Kastenschmidt is an engineer of chemical and bio-technology. He started his career in 2001 as project engineer at the PHAST GmbH in Homburg/Saar. After working in the GMP processes unit within the pharmaceutical analytical development at Merck for 10 years, he joined the development QA in 2016, where amongst other things he is responsible for qualification of analytical instruments, production equipment / facilities and validation of IT-systems.

PHILIP LIENBACHER,
Shire, Vienna, Austria
Philip Lienbacher started his career within Shire (previously Baxter/Baxalta) in 2008 in Vienna. Since then he held a variety of roles inside quality. In 2014, he accepted the position of Manager Global Material Lifecycle Management Systems and is responsible for a team of process experts and project managers. His responsibility includes the global ownership for Receiving & Inspection as well as the general testing- and method deployment-strategy in the company.

ROLAND MIKSCHE
MiRo Consulting Vienna, Austria
After more than 15 years driving CSV, data integrity and all global IT projects within the Quality Assurance Department of Shire, he implemented EBM, an electronic batch management system, at Shire and afterwards, as Senior Consultant of HGP Pharma Consulting, at a customer in Germany. He made his final exam in biochemistry in Vienna, Austria, worked as analyst in accredited laboratories and as a sales and service expert for scientific equipment.

Social Event

In 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.

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, 27 February – 1 March 2019, Budapest, Hungary
☐ Yes, I also want to participate in ECA's Education Course **Reduced Sampling/Reduced Testing** on 25-26 Februray 2019

☐ 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
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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)

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Wednesday, 27 February 2019, 9.00 h - 18.00 h
(Registration and coffee 08.30 h - 9.00 h)
Thursday, 28 February 2019, 08.30 h - 18.00 h
Friday, 1 March 2019, 08.30 h - 16.00 h

Venue

Hilton Budapest City
Váci út 1-3.
1062 Budapest, Hungary
Phone +36 1 288 5500
Email Info.budapest-city@hilton.com

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
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.

Would you like to safe money?

If you register for ECA's Education Course Reduced Sampling / Reduced Testing from 25 -26 February 2019 at the same time, you will receive a 350 EUR discount. This is not valid for EU GMP Inspectorates.

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
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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.:
Mr Rouwen Schopka (Organisation Manager) at +49 (06221/84 44 13, or per e-mail at schopka@concept-heidelberg.de

ECA Education Course

Reduced Sampling/Reduced Testing

25-26 February 2019, Budapest, Hungary

Directly before this ECA Education Course Analytical Instrument Qualification on 25-26 Februray 2019 there will be the ECA Education Course **Reduced Sampling/ Reduced Testing** with these topics:

- Regulatory Requirements for Sampling Procedures
- Design and Qualification of Sampling Areas for Incoming Goods Products
- Supplier Qualification: an important Prerequisite for Reduced Sampling and Reduced Testing
- How to Deal with Divergent Compendial Method Requirements (EP, USP, JP)
- Case Study I: How to Define Inspection Procedures for
  Packaging Materials (Primary and Secondary) in the Incoming Goods Control
- Case Study II: How to Define and Optimise Sampling and Testing Procedures for APIs and Excipients in the Incoming Goods Control
- Sampling and Documentation to make the Supplier liable for Defect Products

Further details will be discussed in a parallel session with 3 workshops.

Further information about this course can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses will receive a 350 € discount (not valid for EU GMP Inspectorates).