ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Jörg Kastenschmidt
Merck, Germany

Philip Lienbacher
Takeda, Austria

Roland Miksche
MiRo Consulting, Austria

Analytical Instrument Qualification

13 – 15 May 2025 | Vienna, Austria

Image: BÜCHI

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

Highlights

- 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

Participate in 3 Workshops!

Objective

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 and a new version is coming up soon.

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 Audience

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>

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

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 / VIS spectroscopy
  - 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

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)

Social Event

On the evening of the first course day, the participants are cordially invited to a dinner. This event is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

Jörg 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
Takeda, Vienna, Austria

Philip Lienbacher started his career within Takeda (previously Baxter/Baxalta/Shire) 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.

This Training Course is recognized for the GMP/ GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Analytical Instrument Qualification, 13 – 15 May 2025, Vienna, Austria

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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 HEIDELBERGwill 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
Tuesday, 13 May 2025, 09.00 h - 17.30 h
(Registration and coffee 08.30 h - 9.00 h)
Wednesday, 14 May 2025, 08.30 h - 17.15 h
Thursday, 15 May 2025, 08.30 h - 15.00 h

Venue
Doubletree by Hilton Vienna Schonbrunn
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110
Email info@doubletreevienna-schoenbrunn.at

Fees (per delegate, plus VAT)
ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
The fee is payable in advance after receipt of invoice and includes 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/POG when you have registered for the conference. Reservation should be made directly with the hotel.
Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21761.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Ms Anne Günster (Operations Director) at
+49(0)62 21/84 44 50, or at
guenster@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Ms Manuela Luckhaupt (Organisation Manager) at
+49(0)62 21/84 44 66, or at
luckhaupt@concept-heidelberg.de