



## Speakers



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# Analytical Instrument Qualification



Live Online Training on 14 – 16 April 2021



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



Q&A Sessions and Exercises  
ensure Interaction

## 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.

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

Practical examples and exercises will allow the participants to discuss key areas of interest.

## 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

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- 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

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- 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

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



### PRACTICAL EXAMPLES / EXERCISES I

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

### Risk Assessment in Analytical Laboratories

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- 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



## PRACTICAL EXAMPLES / EXERCISES II

Topic: Qualification / Risk Analysis of pH Measuring Instruments

### Calibration Management

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- 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

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- 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

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- 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

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

### Balances and Weighing Processes

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- 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)



## PRACTICAL EXAMPLES / EXERCISES III

Topic: Balances

### Qualification of RAMAN / NIR / FT-IR

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

### Volumetric Apparatus (Pipets, Dispensers, etc.)

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- Selection of suitable apparatuses
- Qualification / calibration
- Volumetric laboratory glassware

### Assurance of Controlled Temperature and Humidity

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- 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

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- 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

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- 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

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- 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)



### PRACTICAL EXAMPLES / EXERCISES IV

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



### Q&A sessions

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Q&A sessions ensure interaction and that your questions are answered.



### GMP Certification Programme Certified Quality Control Manager

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. 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.

## 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.

### Your Benefits Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.



Reservation Form (Please complete in full)



## Analytical Instrument Qualification | Live Online Training on 14 – 16 April 2021

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

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- 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.

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## Date of the Live Online Training

Wednesday, 14 April 2021, 9.00 h - 17.30 h  
Thursday, 15 April 2021, 09.00 h - 17.30 h  
Friday, 16 April 2021, 09.00 h - 15.30 h  
All times mentioned are CEST.

## Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.

At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

## Fees (per delegate, plus VAT)

Non-ECA Members: EUR 1,990.-  
ECA Members: EUR 1,790.-  
APIC Members: EUR 1,890.-  
EU GMP Inspectorates: EUR 995.-  
The conference fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. 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.  
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