ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Jörg Kastenschmidt
Merck, Germany

Philip Lienbacher
Takeda, Austria

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Analytical Instrument Qualification

3 – 5 March 2020 | Prague, Czech Republic

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 4 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.

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-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

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)

Social Event

In the evening of the first day, you are cordially invited to a social event. This 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.

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GERMANY

Reservation Form (Please complete in full)

Analytical Instrument Qualification, 3 – 5 March 2020, Prague, Czech Republic

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:
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- Cancellation until 1 weeks prior to the conference 50 %
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Tuesday, 3 March 2020, 9.00 h - 18.00 h
(Registration and coffee 08.30 h - 9.00 h)
Wednesday, 4 March 2020, 08.30 h - 18.00 h
Thursday, 5 March 2020, 08.30 h - 16.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 261 191 111
email prague@corinthia.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.

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 message. Or you register online at www.gmp-compliance.org.

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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