Date of the Conference
Tuesday, 18 November 2025, 09.00 - 17.00 h
Wednesday, 19 November 2025, 08.30 - 12.45 h

All times mentioned are CET.

Technical Requirements
We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

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.

Fees (per delegate plus VAT)
ECA Members € 1,690
APIC Members € 1,790
EU GMP Inspectorates € 945
Non-ECA Members € 1,890
The conference fee is payable in advance after receipt of invoice and includes conference documentation.
VAT is reclaimable.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone: +49 (0) 6221/84 44 0
Fax: +49 (0) 6221/84 44 34
Email: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Sven Pommeranz
(Operations Director)
Phone: +49 (0) 6221/84 44 47,
E-Mail: pommeranz@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Ms Julia Grimmer
(Organisation Manager)
Phone: +49 (0) 6221/84 44 44,
E-Mail: julia.grimmer@concept-heidelberg.de

Registration

To register to the Equipment Qualification Forum 2025 please use the QR Code below or visit www.qualificationvalidation.gmp-compliance.org.

Good Practice Guide

All delegates receive the Good Practice Guide Qualification and Validation Version 3.0
- A guide to effective qualification based on Customer - Supplier Partnership.

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
- 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 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 July 2022).

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.

LW/13082025

Equipment Qualification Forum 2025

Update Validation and Qualification Good Practice Guide

18/19 November 2025, Live Online

All delegates receive ECA´s Qualification and Validation Good Practice Guide 3.0

Highlights

- Knowledge Management in Validation Life Cycle: Inspector´s Expectations
- GEP – the Basis for a Qualification
- Evolution of the Qualification and Validation Practices since its Inception
- AI – "Prompt": Artificial Intelligence, qualify yourself! – Or How Else?
- User Requirement Specification: The Biggest Risk — or the Greatest Opportunity?
- "Pixi-Booklet" – an Easy Way to Share Qualification Information with Suppliers
- Case Study Lean VMP for Qualification and Validation
- Fleet Management – A New Streamlining Concept for Qualification

This conference is recognised for the ECA GMP Certification Programme „Certified Validation Manager". Please find details at www.gmp-certification.eu

ECA Academy
Your GMP/GDP Information Source

Welcome

Dear Colleagues,

Last year the ECA has launched its Good Practice Guide on Qualification and Validation in the version 3.0. This year the group wants to go deeper in the practical implementation of the guide.

Part of this forum is also a survey for the further development of the guide.

Best regards,
Ralf Gengenbach
Chairman of the Validation Group

Overview

Objectives

Qualification and Validation regulations have changed in both Europe and USA in recent years. Many pharmaceutical companies and suppliers are still using methods and documentation from previous practice to prevent changing all procedures already set. Still many companies have very little integration between their activities, so the overall qualification and validation effort is complicated, expensive and time consuming. But some companies have leveraged their qualification and validation programs to a fully integrated approach, as the EU Annex 15 and the FDA Process Validation guide enables.

Qualification is an activity with a history of more than 25 years, but it is still hotly debated. Even modern approaches, aimed at time and cost optimization, do not seem to bring about the expected improvement. A non-harmonized terminology emerges as one of the main problems, especially when it comes to the integration of good engineering practice/commissioning activities with qualification activities. An attempt to create clarity here could be a signpost for a future optimized approach. This attempt will be made in the context of this forum.

The Forum is also about time saving qualification activities. Suppliers are an important factor in this modern approach. And therefore the ECA has developed a Good Practice Guide Qualification and Validation - **a guide to effective qualification based on Customer – Supplier Partnership".**

The speakers are team members or reviewers of the guide. So you have the opportunity to discuss the contents, technical aspects of the guidance document, its scope and practical application during Q&A sessions and a survey. All delegates will receive a copy of the current version free of charge as download. **Case studies** explain how to work together with suppliers. At a red thread the forum shows that based on knowledge management the risk assessments lead to URSes and further qualification activities. And then GEP interacts with the qualification activities. One lecture focuses on Artificial Intelligence and two cases studies show modern approaches like Lean VMP and Fleet Management. Especially for suppliers a "Pixi"-Booklet is developed from the group and will be presented.

Background

Qualification of equipment has been mandatory since the late 80s (FDA Guideline on Process Validation) and the early 90s (EU GMP Guide). Due to inspection results at that time, qualification activities increased significantly and very often, the focus on the patient was lost. The original purpose behind qualification, which is to show that equipment is fit for its intended use, was lost. A white paper from the ISPE "Risk-based qualification for the 21st century tried to amend this. With reference to this paper, ECA´s Validation Group has now further developed their Good Practice Guide Qualification and Validation. This guide is supposed to assist pharmaceutical companies and suppliers with how to qualify equipment in a lean way.

Target Audience

Everyone who may be influenced by the Annex 15 revision and FDA Process Validation Guidance regarding Qualification/Verification and Process Validation activities and want to see how an integrated approach to qualification and validation can enable successful, lean projects. Also addressed are pharmaceutical companies, API and excipients manufacturer and of course equipment suppliers and engineering companies.

Moderator

Ralf Gengenbach, *Chairman of the Validation Group*

Programme

Introduction to ECA´s Good Practice Guide Qualification and Validation

- Development of ECA´s Qualification and Validation Good Practice Guide
- Overview of Version 3.0

Knowledge Management in Validation Life Cycle: Inspector´s Expectations

- What does Knowledge Management mean in GMP-environment
- Toolbox for management
- Which data are essential?
- Focus: Qualification & Validation
- How to assure lifecycle performance

GEP – the Basis for a Qualification

- Basic Engineering Workflows (CD, BD, DD – EPCMQ Projects)
- Process-, Equipment Engineers and more (the full picture)
- Key Documents in Engineering Processes
- FAT, SAT and Commissioning
- How a supplier can support qualification
- Typical pitfalls?

Evolution of the Qualification and Validation Practices since its Inception

- General Qualification & Validation History
- First realization in the XX Century
- The US and EU guidances
  - – the FDA 1983, 1987 and 2011 guides
  - – the PIC/S basis
  - – the EU Annex 15, 2001
  - – the new Annex 15 is coming
  - – Separation of the Qualification & Validation tasks
- Dispatching of the Qualification & Validation roles: OEM, Industry, Consultants
- Conclusion: Extension of the scope and extension of the qualificators/validators

AI – "Prompt": Artificial Intelligence, qualify yourself! – Or How Else?

- Differences from conventional software or conventional computer-based systems
- The auditor and (draft) Annex 22 of the EU GMP Guide
- What is different from "normal" data management regarding data integrity? -Qualification/Validation as usual?
- What about the responsibility for AI results?
- How to control the AI Approaches?

Survey for the further Development of the Guide

- Feedback from delegates
- What to improve?

User Requirement Specification: The Biggest Risk - or the Greatest Opportunity?

- The Fundamental Goals of a URS — More Than Just Paperwork
- Between Bestselling Novel and Critical Project Definition: The Intention of a URS
- Lean URS: Minimalist, Focused, Powerful
- Using AI as Co-Author: Smart Support or Risky Shortcut?

"Pixi-Booklet" – an Easy Way to Share Qualification Information with Suppliers

- What is meant with "Pixi-Booklet"?
- Why a Pixi-Booklet for ECA´s Good Practice Guide Qualification and Validation?
- Example of a draft "Pixi-Booklet"

Case Study: Lean VMP for Qualification and Validation

- Continuous Process Verification vs. Classical Approach
- Virtual VMP
- Jidoka-Approach for IPC – is it possible to automate revalidation?

Fleet Management – A New Streamlining Concept for Qualification?

- Primary Definitions
- Proposed Framework for Distributed Manufacturing
- Fleet Management
- Potential Benefits
- A centralised PQS
- Knowledge Management in a Fleet
- Examples out of practice

Feedback to ECA´s Qualification and Validation Good Practice Guide

- Open questions
- Outlook

Speakers

Sebastian Faller

Global Drug Product Fleet Quality Owner, Roche Pharma AG

With over 10 years of experience in the pharmaceutical industry, he holds a degree in pharmacy and has held various leadership positions in Quality & Compliance. In his current role, Sebastian leads the Drug Product Fleet Quality Team, driving overall quality strategy, compliance, and PQS utilization. Simultaneously, as the Functional Head of Central Certification at Roche, he leads a team of Qualified Person, overseeing all GMP activities related to certification and quality oversight of commercial EU products.

Ralf Gengenbach

Managing Director, Gempex

Ralf Gengenbach is founder and managing director of gempex Co. Ltd., Germany. He was active, among others in DIN UA2 (Board for standards 'biotechnology'), and DECHEMA. He is chairman of VIP3000 as well as of the ECA Validation Interest Group and has published many articles and a book about Qualification. He is still involved in many qualification projects for newly to build factories and active world-wide as 3rd party auditor.

Dr Rainer Gnibl

GMP Inspector, District Government of Upper Bavaria, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health.

Dr Christian Grote-Westrick

Head of Quality Assurance, B. Braun Avitum AG

Dr Grote-Westrick is Head of Quality Assurance, Responsible Person and Lead Auditor. After several positions in the pharmaceutical and medical device industry, he has been responsible for GMP/GDP compliance at B. Braun since 2013. He is a member of the Board of Directors of the European GDP Association.

Maik Guttzeit

Freelance Consultant

For almost 20 years Maik Guttzeit was Team Leader Validation at GEA which provides customized GMP Lyophilizer systems. He is member of the GAMP® D-A-CH committee, of ASME BPE Subcommittee on System Design and also of the ECA validation group. In 2018 he joined Bayer AG, initially as Global Technology Manager Aseptic and Sterile and later as principal expert for C&Q concepts. Maik is currently working as a freelance Senior Expert for GMP Lyophilization and Aseptic Projects.

Dr Timo Kretzschmar

Owner, Senior Consultant, TiKrESolution

Since 2003 Dr Kretzschmar has been working in the GxP field. He was Head of Quality at a GLP/GMP-certified laboratory CRO and lecturer for GxP quality processes at various universities in Austria. From 2016 to 2019, T. G. Kretzschmar was an inspector for GLP and computerised systems / data integrity under GxP at the Austrian pharmaceutical authority AGES/ BASG. Since 2019, Dr. T. G. Kretzschmar has been working in GxP Consulting as well as a GxP auditor and trainer for various consulting companies, since 2024 increasingly on a self-employed basis. Since 2024 he took over again the responsibility as Head of Quality at a GLP/GMP-certified laboratory CRO in Baden near Vienna.

Dr Jean-Denis Mallet

former Head of the French Inspection Department, ECA Advisory Board, NNE Pharmaplan

Jean-Denis Mallet was the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. Now he is member of the ECA advisory board and works for NNE Pharmaplan.

Dr Christian Siegmund

Fleet Program Owner for Drug Product, Hoffmann-La Roche

Christian Siegmund PhD. is a pharmacist by education and works for over 26 years for Hoffmann La Roche. Most of the time he was engaged within aseptic filling (incl. heading 2 aseptic fillings for more than 10 years). Beside of this Christian holds lectures on the topic "Quality management in pharmaceutical industry" at the University of Basel and ETH Zürich for seven years. His actual responsibility lies in the development of the Fleet Management Program within Hoffmann La-Roche, setting up company structures, principles, strategies and defining framework for Fleet Management.

Rafael de Souza

Manager CQV and Senior Project Quality Manager, Excyte Switzerland AG

Since 2004 he has gained extensive experience in good manufacturing practice (GMP), quality assurance and commissioning, qualification and validation (CQ&V) within the pharmaceutical and biotech industries. He has been working on projects with a focus on leading quality management and C&Q activities in line with traditional risk-based principles for Commissioning and Qualification, as well as Science and Quality by Design approaches (e.g., ASTM E-2500). Since 2017, Rafael has been an active member of the European Compliance Academy (ECA) Validation Group. In 2020, the ECA group published the first edition of the "Integrated Qualification and Validation" guideline, aimed at advancing CQ&V practices across the pharmaceutical community.