ECA Academy
Your GMP/GDP Information Source

Speaker

Dr Wolfgang Schumacher
SPC, formerly F. Hoffmann-La Roche, Switzerland

Validation/Qualification for Beginners

Live Online Training on 05 May 2026

Basics about Qualification and Validation

Highlights

- Regulatory Requirements
- Risk Assessment
- Qualification
- Process Validation
- Analytical Method Validation
- Change Control

Objective

In order to give you a concentrated one-day **overview** of the cGMP requirements regarding Process Validation and Equipment Qualification, the ECA has designed the practice-oriented 1-day GMP Education Course "Validation/Qualification for Beginners" for you. There will be also short overviews about Cleaning Validation and the Validation of Computerised Systems.

Among other things, these questions will be discussed:

- Differences between URS and FDS?
- Are FAT and SAT mandatory? If not, how to use?
- Do we have to follow an 8-step qualification process in Europe?
- Is a PQ mandatory?
- Is an integration of ASTM 2500 in Annex 15 requirements possible?
- How to handle Equipment Qualification with equipment in use?
- Requalification – when, what, how often?
- What are the differences between PQ in FDA requirements and PQ regarding Annex 15?
- Are PPQ and Process Validation the same?
- What are differences between Continued Process Verification (US) and Ongoing Process Verification (EU)?
- Continuous Process Verification – a new concept?
- Are statistics mandatory in Process Validation?
- PDE – a "new" concept in Cleaning Validation
- What has changed with GAMP 5 revision 2?
- Analytical Method Validation on the move – ICH Q14

Background

Process Validation and equipment qualification are essential requirements in GMP. With the revisions in FDA Process Validation Guidance and the EU GMP Guide Annex 15 a Process Validation life cycle has been introduced. Risk analysis is the new "buzz word" in validation and qualification.

In the majority of GMP inspections, Process Validation and Equipment Qualification aspects are covered. Although, there are guidelines from the EU (Annex 15) and the FDA (Process Validation Guidance) details are still open or not well explained. Also, other regulatory guidelines (WHO, ASTM...) don´t give hints in details. So, there is a lack of interpretation.

Target Audience

The addressees of the event are beginners involved in Process Validation and Equipment Qualification activities such as Subject Matter Experts for validation, heads of quality assurance, engineering department heads, etc. It also addresses members of validation teams (e.g. engineers, chemists, pharmacists, microbiologists) as well as representatives of the plant engineering department and consultants, who want to get an insight of the topics.

Programme

Regulatory Requirements

- EU GMP guideline and annexes
- PIC/S guidelines
- FDA 21 CFR 210/211 and Guidances for Industry/Guide to inspection of...
- WHO
- Validation Master Plan
  - Requirements according Annex 15

Risk Assessment

- Why is risk assessment necessary?
- ICH Q9 revision 1
- Risk assessment techniques and tools
- Case study

Qualification

- Annex 15 requirements
- FDA requirements
- URS, FDS, DQ, FAT, IQ, SAT, OQ, PQ – how the stages fit together
- How to handle qualification logistics?
- Re-qualification – when, what, how often?
- Qualification of equipment in use
- ASTM 2500 vs Annex 15
- When does calibration happen?

Process Validation

- The validation life cycle
- Prospective vs concurrent validation
- Are 3 runs still state of the art?
- What does Hybrid Approach mean?
- Revalidation vs. Continued Process Verification and Ongoing Process Verification
- Similarities/differences between Process Validation expectations in US and EU
- Overview: Cleaning Validation
- Overview: Validation of computerised systems

Analytical Method Validation

- ICH Q2 R1
- Verification of compendial methods
- Method transfer
- Recap of the most important analytical parameters

Change Control

- GMP vs Marketing Authorisation – an important distinction during Change Control
- The Change Control Process
- Who is involved?
- Like-for-like changes

Q & A Sessions

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

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Speaker

Dr Wolfgang Schumacher
SPC, formerly F. Hoffmann-La Roche Ltd., Switzerland

Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions in QA and escorted lots of inspections. From 2001 to 2016 he was Head of the department of Quality Computer Systems in Tech. Ops. at F. Hoffmann-La Roche, Basle. He is a member of the ECA Advisory Board.

Testimonial

"I would like to mention that it was an amazing course and was very useful and knowledgeable one indeed. Thank you!"
Sruthi Thelakkat Chathoth, Thermofisher

Your Benefit

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

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Reservation Form (Please complete in full)

Validation/Qualification for Beginners, Live Online Training on 05 May 2026

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)

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date Live Online Training

Tuesday, 05 May 2026, 09.00 - 16.15 h
All times mentioned are CEST.

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.

Fees (per delegate, plus VAT)

ECA Members € 1,090
APIC Members € 1,190
Non-ECA Members € 1,290
EU GMP Inspectorates € 645
The fee is payable in advance after receipt of invoice.

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 22430.

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.

You cannot attend the Live Event?

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Organisation and Contact

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