ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speakers

Ralf Gengenbach
Gempex

Dr Rainer Gnibl
GMP Inspector

Alejandro Parisi
Roche Diagnostics

The Use of Artificial Intelligence in Qualification and Validation

Live Online Training, 24 September 2025

How Artificial Intelligence can safe time and money in Q&V Activities

Highlights

- The Use of Artificial Intelligence in the Pharmaceutical Environment: A GMP Inspector's Perspective
- The Use of Artificial Intelligence in Qualification and Validation: Possibilities and Limitations - an Industry Representative's Perspective
- Case Study: Use of Artificial Intelligence in Equipment Qualification

AI - Supporting in Qualification & Validation

Objective

A GMP inspector establishes the necessary regulatory framework so that artificial intelligence can be used in a GMP-compliant manner. He will provide an insight into the planned changes to Annex 11 and discuss the new Annex 22 on artificial intelligence. An industry representative will then give an overview of the possible applications of artificial intelligence in the area of qualification and validation. Current practical experience in the pharmaceutical industry will be discussed. Another industry representative will then present the use of artificial intelligence in equipment qualification in a "live performance". He will also highlight potential savings. Two question-and-answer sessions will provide the opportunity to discuss this complex topic.

Background

Hardly any other topic is currently being discussed in the pharmaceutical industry as much as the use of artificial intelligence. The potential applications appear to be vast, the uncertainty even greater. There are a lot of terms "buzzing around": artificial intelligence vs. machine learning vs. deep learning. There are questions:

- How to ensure data integrity in the field of artificial intelligence?
- What regulations on artificial intelligence actually exist?
- What roles do GAMP 5 Annex 11, the EMA reflection paper on artificial intelligence and the upcoming Annex 22 on this topic play?
- What tests are necessary to be able to use artificial intelligence?
- What possible applications are there in the area of qualification and validation?
- Where are the limits to the use of artificial intelligence?
- What framework conditions must be in place in the company so that artificial intelligence can be used in compliance with GMP?

The one-day online compact seminar "The use of artificial intelligence in qualification and validation" aims to help clarify these questions.

Target Audience

It is aimed at those interested in the use of artificial intelligence in the field of qualification and validation, but who also want to know which requirements are necessary from an official point of view before use. Explicitly addressed are e.g. quality management/quality assurance managers, validation officers, production managers, etc.

Programme

The Use of Artificial Intelligence in the Pharmaceutical Environment: a GMP Inspector's Perspective

Basic Terms

- Artificial intelligence vs machine learning vs deep learning
- IT validation and life cycle

Basic EU Framework Conditions

- Preconditions: The Pharmaceutical Quality System according to ICH Q10
- Data Governance
- Data Integrity
- GAMP 5

Specific Requirements

- EMA Reflection Paper on Artificial Intelligence
- Annex 11 Revision Draft document
- Annex 22 Draft
- GAMP 5 D11
- Supporting framework conditions (QRM, data integrity, change management)

Focus: Testing

- Test types
- Test structures
- Test plan
- Test execution
- Test report

The Use of Artificial Intelligence in Qualification and Validation: Possibilities and Limitations - an Industry Representative's Perspective

Why use Artificial Intelligence for Qualification and Validation?

- Perfect results
- Time savings

Free Systems vs. in-house Systems

- ChatGPT
- DeepSeek
- on-house systems

Previous Experience with the Use of Artificial Intelligence in the Area of Qualification and Validation

- Plan creation using artificial intelligence
- Report creation using artificial intelligence
- Problem ghosting

Case study: Use of Artificial Intelligence in Equipment Qualification

Creation of a User Requirement

- Duration
- Accuracy of results
- Cost savings
- Internal company procedures to be GMP-compliant

Speakers

Ralf Gengenbach, Managing Director, Gempex, Germany

Ralf Gengenbach is a chemical engineer with more than 30 years of practical experience in GMP and especially in the field of qualification and validation. He is founder and managing director of gempex GmbH, a global acting GMP consulting company. He is president of the VIP3000, an association for suppliers to the pharmaceutical industry. He was active for the development of technology as well as qualification relevant standards in different organisations, among others DIN UA2 (Board for standards 'biotechnology'), DECHEMA, and VCI. He has published beside many technical articles a book about Qualification and Validation, published by Willey and still serving as a basic standard. Since 2022 he has taken the chair of ECA's Validation Group.

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.

Alejandro Parisi, People Lead MSAT, ROCHE Diagnostics, Germany

Alejandro Parisi is a chemical engineer and started his career in the pharmaceutical industry 30 years ago. He joined Roche in Penzberg as a Qualification Engineer in 2004 and, among other things, led the local qualification and validation team for 7 years. In 2017, he moved into the role of "Validation Network Lead" and in this function, he introduced, among other things, a paperless software system ("eVALRoche"), including standardization, for all Roche Pharma sites. Today, he is at Roche Diagnostics Operations as a People Lead in the MSAT organization responsible for CAPEX Projects."

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GERMANY

Reservation Form (Please complete in full)

The Use of Artificial Intelligence in Qualification and Validation, Live Online Training, 24 September 2025

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.

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 of the Live Online Training

Wednesday 24 September 2025, 09.00 - 15.45 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 conference 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 22271.

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.

GMP/GDP Certification Scheme

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.

Organisation and Contact

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

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