ECA Academy
Your GMP/GDP Information Source

Speakers

Peter Hackel
Takeda, Austria

Dr Frank Hanakam
QuaSyCon

Manfred Karner
Takeda, Austria

Torsten Kneuß
Bayer, Germany

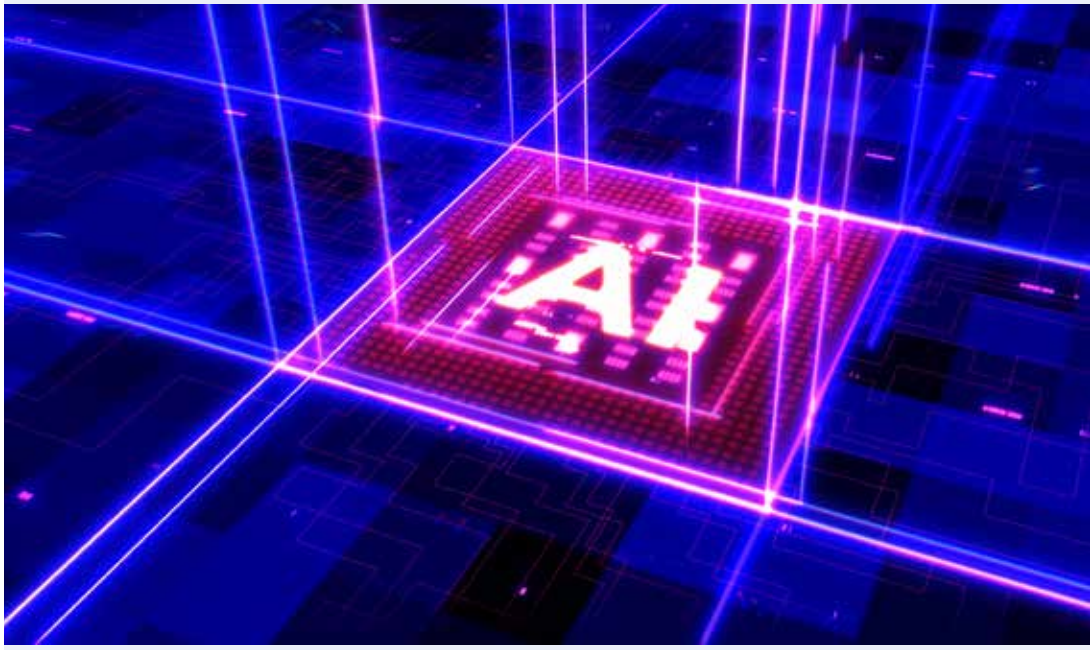
Philip Lienbacher
Takeda, Austria

Simon Schäfermann
GMP Inspector, RPR Tübingen, Germany

GMP meets AI

How to use Artificial Intelligence in Quality Assurance and Quality Control

Live Online Training on 17/18 February 2026



Highlights

- AI in the GxP Environment
- How to train a GPT; Prompt Engineering
- How to Use GPT and digital Tools to Support Daily Work in QA; Application Examples
- Automation of Processes with the Help of AI and Digital Tools
- Use of GPTs in QC for Records, Reports and Qualification/Validation Documents
- Batch Release; Examples of Support from AI

Background

In this seminar, you will learn about the possibilities of using artificial intelligence in the areas of quality assurance and quality control in the pharmaceutical industry.

You will learn

- How GPT can be used for daily work with GMP documents
- How processes can be automated with the help of AI and digital tools
- Which prompting techniques lead to good results
- How AI can be used in pharmaceutical quality control
- What support AI applications can provide for batch release

You will also receive the latest information from ISPE's new GAMP AI Good Practice Guide

Now that the use of artificial intelligence in medical diagnostics has already found its way into the field of imaging procedures, the use of AI applications in the GxP environment is expanding rapidly. Specifically defined chatbots can be used, for example, to search for information on websites. Specially trained GPTs provide support in handling GMP-regulated documents such as qualification/validation documents, stability protocols or trend reports.

Target Audience

This seminar is aimed at those responsible in the areas of quality assurance and quality control in the pharmaceutical industry who use AI applications in their areas or decide on their use.

Programme

Use of AI in the GxP Environment from a GMP Inspector's Perspective

- EU GMP Guideline Annex 11
- Concept Paper Revision of Annex 11
- EMA Reflection paper on the use of Artificial Intelligence (AI)
- Guidelines from the pharmaceutical world
- Inspection practice

Use of AI in the GxP Environment - what is Required to Generate the Necessary Trustworthiness

- Potentials and challenges in the use of AI in the pharmaceutical industry
- Current laws and guidelines on AI
- Some important AI terms and concepts
- Data are the true indicators of performance
- What role do humans play and what roles are required?
- From the use case to the right AI system, validation of AI application using a life cycle model
- Risk and quality management
- Briefing on ISPE's GAMP AI Guideline

Generative Pre-Trained Transformer (GPT) - Use in the Pharmaceutical Industry

- Potential applications
- Benefits and challenges
- Training and working methods of a GPT
- Regulatory aspects
- Integration into the corporate application landscape
  - Use of platforms
  - Use of own data sources to increase fact security (RAG: Retrieval Augmented Generation)
  - Steering GPT systems in the right direction (Guardrails)

Use of AI and Digital Tools to Support Daily QA Work

- Digital Transformation – a journey
- Use of GPT (Generative Pre-trained Transform) - (ChatGPT, MS Copilot)
  - Automated creation of documents/presentation
  - Translations / rewording of texts
  - Use suggestions from Chat GPT, e.g. to define CAPA measures
- Document analysis with GPT
  - Summarizing and extracting key information from multi-page reports (e.g. FDA 483s, guidelines)
  - Creation of meeting notes based on meeting transcripts and extraction of action items
- ChatBots or user-defined GPT applications
  - Creation of GPT-ChatBots for information search
  - Searching authorities' sites to obtain information
  - Search for references to audit observations specifically in the online versions of guidelines
  - Assistance on questions about process from process instructions, work instructions

Digitalization/Automation as the Basis for the Efficient Use of AI in QA and QC

- Basics for QC & QA on IT framework - digitalization - automation - use of AI
- Generation of raw data and data systems
- Real-life automation examples QA & QC

Application Examples for AI in QA - from the Idea to Use

- Collection and benefit assessment of AI use cases
- Development of solutions
  - Automation pipelines
  - No-code/low-code tools
- Application examples in QA
  - Audit management
  - Complaint management
  - Deviation management
  - Quality management documentation

Digitalization/Automation and AI in QA

- Application examples Batch release
  - Batch tracking & visualization
  - Authority documents
- Cooperation between QA and production
  - GEMBA and GMP tours: automation example

Automation of Processes Using AI and Digital Tools

- Microsoft Power Platform
  - Creation of applications and automations without in-depth programming knowledge
  - Connection of AI elements with self-created applications and automations
- Data correctness – key for success
- Automation of tracking and managing processes (Audit process as an example)
- Using machine learning to automatically extract information from pdfs - Supplier Notification of Change (SNC) as example
  - GPT support for processing SNCs
  - Translation of documents transmitted in the respective national language
  - Support in the classification of SNCs in terms of criticality through AI recommendations
- Use of GPT for the automatic generation of audit reports based on notes

Basics of Prompt Engineering

- Introduction ChatGPT
- Introduction to prompt engineering
- Prompt techniques
  - Zero-shot prompting, few shot prompting
  - Chain-of-Thought
  - Reverse engineering prompting
- Risks and misapplications

Use of AI in QC – Guidelines

- QA processes and their specific needs
- Step by step approach for automation/digitalization
- Use-Cases of AI and Automation in QC
  - GPTs in QC for protocols, reports and qualification/ validation documents
  - Investigation reports, stability protocols, qualification of equipment or standards, method validation, method transfer, responses to authorities
  - What are the basics of the use/application case?
  - KPI review and trend reports

From Data Generation to Use - Opportunities and Potential Pitfalls of Digitalization

- Responsibility: Why data governance starts with the business process
- System architecture: How we can make data usable and why one way is not always the right way
- Data quality and integrity: Use of data in the GxP environment and how we can ensure trust in our data
- Utilization: Systematic and sustainable implementation of digital tools, also through citizen development.digital tools, also through citizen development

Speakers

Peter Hackel, Takeda

Head of Data, Digital and Technology (DD&T) at Takeda Vienna and thus responsible for the digitalization strategy and digitalization projects of Takeda's largest production site.

Frank Hanakam, QuaSyCon

Consultant with over 25 years of practical experience in development, production, quality, and regulatory affairs for biotherapeutics and biosimilars. Focus on cost-effective, quality-assured, and regulatory-compliant CMC solutions throughout the entire product lifecycle.

Manfred Karner, Takeda

After holding various management positions in local quality, he has been working in global quality management since 2014, where he is currently Head of Global Supplier Quality Management (GSQM).

Torsten Kneuss, Bayer AG

Quality Product Steward Medical Devices and Head of Project Office Medical Devices, responsible for devices and combination products within Bayer AG.

Philip Lienbacher, Takeda

Manager Global Material Lifecycle Management Systems and responsible for a team of process experts and project managers. His responsibilities include the global ownership for Receiving & Inspection as well as the general testing and method deployment strategy in the company.

Simon Schäfermann, GMP Inspector

Responsible for national and international EU GMP inspections and member of the Expert Group on Computerized Systems (EFG11) of the competent authorities of the federal states.

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Reservation Form (Please complete in full)

GMP meets AI
Live Online Training on 17/18 February 2026

Title, first name, surname

Department | Company

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City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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If you cannot attend the conference you have two options:
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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

Tuesday, 17 February 2026, 9.00 – 17.00 h
Wednesday, 18 February 2026, 8.30 – 14.30 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.

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
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 22452. To avoid incorrect information, please give us the exact address and full name of the participant.

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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