ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers


Ib Alstrup
Danish Medicines Agency (DMA)


Victor Bechmann
Kuatro group, Denmark


Dr Philipp Fey
Boehringer Ingelheim, Germany


Kevin Françoisse
Ellion x Sagacify, Belgium


Jorge Gil-Hernandez
Boehringer Ingelheim, Germany


Torsten Kneuss
Bayer, Germany


Felix Krumbein
Head ECA Visual Inspection Group, Germany


Stefan Münch
Körber Pharma Consulting, Germany


Dr Rolf Roth
Merck Healthcare, Germany


Yves Samson
Kereon, Switzerland


Dr Torsten Schmidt-Bader
moveproTEC Compliance & Innovation Advisory, Germany


Dr Jörg Stüben
Boehringer Ingelheim International, Germany


Daniel Wolf
Ulm University Medical Center, Germany

Annex 22 / AI Conference 2025

With a 1 Day Pre-Conference Course on **Basics of AI**

4 and 5-6 November 2025 | Copenhagen, Denmark

Save €400,- by booking both courses!

Highlights

- **The brand new draft of EU GMP Guide Annex 22 ‚Artificial Intelligence'**
- What Questions to expect during an Inspection?
- How to apply GxP Regulations to AI (Artificial Intelligence) and ML (Machine Learning)
- Which Validation Approach is applicable to AL/ML Systems?
- What are typical Risks and Opportunities?
- What are the (current) Limitations of AI/ML Applications?
- Case Studies from:
  - Boehringer Ingelheim
  - Kuatro
  - Merck
  - Novo Nordisk

Programme: Pre-Conference Course on Basics of AI

Objectives

What can you expect in the Pre-Conference Course?

- Get to know the basics of AI (Artificial Intelligence) and ML (Machine Learning),
- Learn about the importance of data and models,
- Risk management and validation; how should these classic pharmaceutical topics be considered and applied in the context of AI and
- What are the applications and limitations in the GxP environment? Learn about the current state of development.

Background

In addition to the general public, the topic of artificial intelligence now also has the healthcare industry in its grip. In order to assess and apply the technology in a meaningful way, it is important to understand the basics. What technologies is AI based on? What is the significance of data - data quality - data availability and models? The pre-training course offers you a first introduction to the topic.

Target Audience

The pre-conference is aimed at managers and interested parties from the pharmaceutical industry, suppliers and service companies who want to find out about the basics of AI and its possible applications in the pharmaceutical environment.

Programme

Introduction to Artificial Intelligence (AI)

- History of AI
- Types of AI
- Current situation
- Real life examples

Introduction to Machine Learning (ML)

- Technological basics
- Different learning / training methods
- Example use cases

Data and Models

- Classification of data and models
- Regulators' thinking in the context of data and models
- Data quality considerations and challenges
- Data handling practices: Splitting, selection and synthetization
- Model version management and model updates

Generative AI

- Introduction to Large Language Models (LLM)
- Tailoring LLMs for your business case
- Typical risks when using LLMs
- Performance evaluation and validation strategies for LLMs

Risk Management for AI/ML

- Basics of a ML Risk and Control Framework
- Applying QRM to development and operation of AI applications
- Using hazard clusters to guide the risk process

Validation Approaches

- Maturity: Increasing autonomy and transferring control
- Governance: Developing and operating AI solutions in GxP-regulated areas
- Lifecycle approach and Good Machine Learning Practice (details)

AI / ML in Pharma, Biotech, and Medical Devices

- Challenges for the Life Science industry
- The GAMP® perspective on AI/ML
- The EU AI Act and its impact on the Life Science industry

Programme: Annex 22 / AI Conference 2025

Objectives

- You will gain an overview of the current state of regulatory development with regard to the use of AI in the pharmaceutical industry
- You will be able to better assess the possibilities and limitations of this technology
- You will learn the prerequisites for establishing AI projects in the company
- Case studies from pharmaceutical companies will show you possible areas of application for AI

Background

Since ChatGPT, Bard, Midjourney and others, artificial intelligence (AI) has reached the general public. Opinions fluctuate between absolute euphoria and the evocation of the downfall of humanity. The foundations of AI were laid many years ago and can now be realised on a large scale thanks to the massive computing power available.

The topic has also found its way into the pharmaceutical and medical technology industry. The drafts published by the EU Commission on 7 July 2025 for the new version of EU GMP Annex 11 on computerised systems and the new Annex 22 on AI will also be dedicated to this Topic.

The first applications have now been established in pharmaceutical companies. The interesting question is whether and how this technology is compatible with pharmaceutical regulations, specifications and the expectations of the authorities. Several case studies will look at various possible applications.

Target Audience

The conference is aimed at managers and interested parties from the pharmaceutical industry, suppliers and service companies who decide on the use of AI and (want to) qualify and operate AI applications in a GxP environment.

Programme

Overview of AI in GxP: Capabilities & Opportunities

- General introduction
- (Very) brief introduction to AI & ML
- Drivers (for using AI & ML in pharma)
- Regulations and guidances

AI Limitations and Areas of Concern

- Current situation
- What do you need to watch out for?
- What are the risks?

Current regulatory Situation – the new EU GMP Guide Annex 11 and Annex 22 - and Expectations in the Context of an Inspection

Inspection Readiness

- Overview of supporting processes: data management, risk management, change management
- Have documentation ready – provide reasoning and justifications
- How to setup mock inspections successfully

Aspects of AI Adoption “with and beyond Regulations”

- Regulations and the degree of freedom
- What you may want to consider
- Examples and evaluation criteria

Interactive Presentations

AI in Imaging: An Interactive Introduction with Real-World Examples

- Understand each key step in building an AI model for imaging: data preparation, training, pre-training, testing, and explainability
- Learn through a real-world example: cancer diagnosis and prognosis based on CT scans
- Explore what’s next: opportunities and risks of using large pre-trained multimodal AI models
- Engage actively: think, ask, discuss - your participation shapes the session
- Leave with a clear understanding of how AI can support your own imaging challenges

Basics of Prompt Engineering

- Introduction to ChatGPT and current Large Language Models
- Overview of prompt engineering
- Prompt techniques
  - Zero-shot prompting, few-shot prompting
  - Chain-of Thought
  - Tree of Thought (ToT)
  - Reverse Engineering Prompting
  - Example use cases

Case Studies

Artificial Intelligence (AI) for Discrepancy Managemen

- Detection of clusters based on Natural Language Processing
- Validated AI tools in GxP environment
- Human centric approach to ensure quality and control
- Risk based approach to reduce work-load for investigators

Artificial Intelligence in Pharmaceutical Production – Example: Visual Inspection

- Traditional image processing and its limitations
- Opportunities through the use of artificial intelligence
- Expectations, risks, and requirements for the use of AI
- Planning, Implementation, Operation & Monitoring – a life-cycle approach following the risk-knowledge-infinity cycle
- Documentation of model development: traceability and risk mitigation

Case Studies

AI Coding Agents

- Overview: Evolution of AI coding agents
- State-of-the-Art: Current capabilities and limitations
- Use Cases: Beyond coding
- Outlook & Transfer: Future vision and imaging agent capabilities

AI Deviation Assistant – Enhancing Deviation Workflows

- Deviation management challenges in pharma
- AI-powered solution: Knowledge Graph / LLM RAG
- Key features, benefits, and impact
- Demo and use cases

Validating LLMs for GMP: A Framework for Document-Centric Use Cases

- Risk-based validation strategies for LLM-based systems
- Defining appropriate performance metrics for mixed-content data
- Human-in-the-loop controls to ensure accuracy and compliance
- Considerations for traceability, auditability, and change management

Learning from the Banking Sector: Transfer of AI-based Inspection Tools into GxP regulated Environment

- How we can learn from other industries: Conducting AI-based compliance audits in the banking & insurance sector (example: DORA regulation)
- Goal: The way to systematic and GDPR-compliant document checks without language barrier
- Solution: Fast-track AI-supported inspections of quality management systems in GMP systems
- Why auditors are still mandatory: Checking the implementation status of written standards
- AI never sleeps: Failure-free creation of risk-based compliance inspection reports
- Verification versus GMP validation: The limitations of AI tools in GxP practice

Speakers
Pre-Conference Course on Basics of AI and Annex 22 / AI Conference 2025

Ib Alstrup
GxP IT Medicines Inspector
Danish Medicines Agency (DKMA)
With a background as a software designer and tester, Ib has specific focus and large experience in inspection of validation and operation of computerised systems throughout the GxP areas. He is a co-writer of the new PIC/S guide on Data Integrity and holds a B.Sc. in Electronic Engineering.

Victor Bechmann
Kuatro group, Denmark
Victor is an experienced pharmacist from the pharmaceutical industry, having worked with production as both validation consultant and project manager, delegate QP and most recently as Head of Quality. Currently AI Validation Lead – GxP Sr. Consultant.

Dr. Philipp Fey
Boehringer Ingelheim, Germany
During his PhD, Philipp focused on developing and applying Artificial Intelligence in Tissue Engineering, Biomedicine, and Biophysics. Currently at Boehringer Ingelheim, he is responsible for process and validation management for the global quality management system, with a particular emphasis on interfaces and the integration of AI in GxP environments.

Kevin Françoisse, Ellion x Sagacify, Belgium
Kevin Françoisse is an entrepreneur and AI expert with over a decade of experience helping organizations leverage artificial intelligence to automate complex operational processes. As CEO and co-founder of Sagacify, he leads a team of 30 AI engineers focused on delivering impactful, custom AI solutions - including intelligent agents - for industries such as pharma, insurance, and logistics.

Jorge Gil-Hernandez, Boehringer Ingelheim, Germany
Senior QA Manager for CSA at Boehringer Ingelheim, with more than 10 years' experience in Computer System Validation, QA processes and project management in Pharma industry.

Torsten Kneuss, Bayer, Germany
Since October 2020 he is, as a Quality Product Steward Medical Devices and Head of Project Office Medical Devices, responsible for devices and combination products within Bayer AG.

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.

CONCEPT HEIDELBERG
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Dr Andreas Mangel (Operations Director) at
+49(0)62 21/84 44 41, or at mangel@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at schopka@concept-heidelberg.de.

Social Event

On the first day of the Annex 22 / AI Conference 2025 (5 November), 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.

NEWS

Stay informed with the GMP Newsletters from ECA

The ECA offers various free of charge GMP newsletters for which you can subscribe to according to your needs.

To subscribe, simply scan the QR code on the right or visit www.gmp-compliance.org/gmp-newsletter

Speakers (cont.)

Stefan Münch
Körber Pharma Consulting, Germany

Stefan Münch, Vice President of Validation and Qualification, is responsible for the validation and qualification services of Körber Pharma Consulting. He has more than 25 years of experience in software development (MES) and consulting for the pharmaceutical industry. Furthermore, Mr. Münch is actively engaged in GAMP D-A-CH for many years and member of the steering committee.

Dr Rolf Roth
Merck Healthcare, Germany

Rolf holds dual roles as Head of Data Science and AI for Global Healthcare Operations and Principal Technical AI Lead for the Healthcare sector at Merck KGaA, Darmstadt, Germany. His team develops AI solutions and delivers trainings across Healthcare Manufacturing, Development, Supply Chain, and Quality.

Yves Samson, Kereon, Switzerland

Yves joined the industry where he served as project and site engineer automation. In 2002, he founded Kereon AG. He is member of GAMP® Europe Steering Committee, co-founder and chairman of GAMP® Francophone and edited the French version of GAMP® 4 / 5. Membership: ECA 'DI & IT Compliance Group'.

Dr Torsten Schmidt-Bader
moveproTEC Compliance & Innovation Advisory, Germany

Dr Torsten Schmidt-Bader is Managing Director at moveproTEC and a GMP/GDP lead auditor and compliance advisor. Since 2010 he has been supporting the life science industries and pharma logistic providers with GDP implementation.

Dr Jörg Stüben
Boehringer Ingelheim International, Germany

Joerg has a long track record of leading cross functional large compliance critical projects. In his current function of heading the RIM group at BI he is heavily involved in data management and analytics. He is co-founder of the GAMP D-A-CH Special Interest Group (SIG) AI and member of the GAMP D-A-CH Steering Committee.

Daniel Wolf,
Ulm University Medical Center, Germany

Daniel Wolf conducts research in the area of artificial intelligence in medical imaging. His focus is on deep learning algorithms to support radiologists in diagnosis and prediction based on image data.

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Pre-Conference Course on Basics of AI

☐ *4 November 2025, Copenhagen, Denmark*

Annex 22 / AI Conference 2025

☐ *5-6 November 2025, Copenhagen, Denmark*

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:
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 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 %.

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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/privacy-policy). 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.

Dates & Venue

Pre-Conference Course on Basics of AI
Tuesday, 4 November 2025, 09.00 – 17.00 h CET
(Registration and coffee 08.30 h - 09.00 h CET)

Annex 22 / AI Conference 2025
Wednesday, 5 November 2025, 09.00 h – 18.00 h CET
(Registration and coffee 08.30 h - 09.00 h CET)
Thursday, 6 November 2025 2025, 08.30 h – 16.30 h CET

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone: +45 3396 50 00
E-Mail: guest.copenhagen@radissonblu.com

Fees (per delegate plus VAT)

Fees Pre-Conference Course on Basics of AI
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 and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Fees Annex 22 / AI Conference 2025
ECA Members € 1,990
APIC Members € 2,090
Non-ECA Members € 2,190 |
EU GMP Inspectorates € 1,095
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event including dinner on the first day, two lunches and all refreshments. VAT is reclaimable.

Save money and book both courses:

We will offer you a discount of € 400 if you book both training courses.
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on all conference days, social event including dinner on November, 5th, 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 – or search and register directly at www.gmp-compliance.org under the numbers 22081 (Pre-Conference Course on Basics of AI), 22082 (Annex 22 / AI Conference 2025), 22083 (Pre-Conference Course on Basics of AI + Annex 22 / AI Conference 2025).

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