

Speakers



Dr Arno TerhechteDistrict Government
Münster
(GMP Inspectorate)



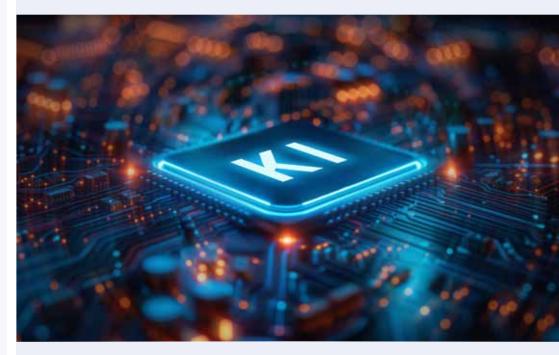
Stefan Münch Körber Pharma Consulting

The new Annex 22 on Artificial Intelligence

Evaluation of the Draft and its Impact on GMP Applications



Live Online Training on 23 September 2025



Highlights

- Objectives and Content of the new Annex 22 'Artificial Intelligence'
- Differences and Overlaps with Annex 11 'Computerised Systems'
- Connection to Chapter 4 'Documentation' of the EU GMP Guidelines
- Evaluation of the Draft Annex 22 from a GMP practice perspective
- Risks and Challenges of AI in GxP Environments: Validation, Bias, Data Sets, Algorithmic Decisions – What do Companies Need to Consider in Terms of Quality and Compliance?
- Opportunities to Influence: Comment Process and Recommendations

In around two hours, two experienced speakers will present key content, interpretations and practical aspects of the draft Annex 22. Participants will have the opportunity to ask their own questions and discuss them with the experts.

Objectives

On 7 July 2025, three important draft documents relating to the EU GMP guidelines were published: the revised version of Annex 11 'Computerised Systems', the new version of Chapter 4 "Documentation" and, for the first time, a separate Annex 22 'Artificial Intelligence'.

The publication of Annex 22 is a milestone – for the first time, a regulatory document is specifically dedicated to the use of artificial intelligence in GxP-regulated areas.

The aim of this event is to analyse and critically evaluate the requirements of the new draft Annex 22 and to place it in the overall context of the applicable GMP regulations. The impact on existing systems and new requirements for the implementation and validation of AI systems will be examined. A particular focus will be placed on the practical consequences for pharmaceutical companies.

Target Audience

This seminar is aimed at specialists and managers from the pharmaceutical industry as well as their service providers and suppliers. It is particularly aimed at those responsible for quality assurance, production, IT, CSV, digitalisation, regulatory affairs and project management in relation to AI systems.

Speaker



Dr Arno Terhechte District Government Münster (GMP Inspectorate)

Since 2003, he has been working as an inspector in the pharmaceutical department of the Münster district government. He is head of EFG 11 'Computer-Assisted Systems'.



Stefan Münch Körber Pharma Consulting GmbH, Karlsruhe

Stefan Münch is Vice President Validation & Qualification for CxV Services. In addition, Mr Münch has been active in GAMP D-A-CH for more than 10 years and has been head of GAMP D-A-CH since March.

Programme Schedule
- Focus on Annex 22 'Artificial Intelligence'

Introduction and Background to Annex 22 Dr Arno Terhechte

- Regulatory context: Why a separate annex on artificial intelligence?
- Development history and objectives of Annex 22
- Overview of the structure and content of the draft
- Distinction from Annex 11 and Chapter 4 'Documentation'
- Assessment from the perspective of the supervisory authorities

Does Annex 22 close the Regulatory Gap? - The two Sides of the Coin - A Detailed Examination Dr Arno Terhechte & Stefan Münch

Joint Discussion of Annex 22 – Paragraph by Paragraph

In an interactive format, the two speakers will examine the contents of Annex 22 step by step - alternating between the perspective of the authorities and that of industry. The aim is to promote a common understanding of the requirements while identifying the practical challenges of implementation. Topics covered include:

- Definition and delimitation of 'artificial intelligence' in the GxP context
- Requirements for training data and model transparency
- Validation and life cycle of AI systems
- Dealing with self-learning systems
- Requirements for documentation, traceability and audit
- Responsibilities and governance for AI applications
- Risk assessment and change control for AI-based pro-

Question and Answer Session and Discussion Moderated by both speakers

At the end, there will be an opportunity to ask the speakers questions and discuss specific aspects, such as:

- Which AI applications are specifically affected?
- What does the annex mean for existing systems?
- What measures should be prepared now?

Benefits for Participants

- Compact overview of the contents of Annex 22 (draft)
- Assessment of regulatory requirements by authorities and industry
- Specific information on implementation and possible stumbling blocks
- Opportunity for direct questions and discussion with experts

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Date of the Live Online Training

Tuesday, 23 September 2025, 14:00h - 16:00h All times mentioned are CEST.

Technical Requirements

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Fees (per delegate plus VAT)

Non-ECA Members EUR 590 ECA Members EUR 490 APIC Members EUR 540 EU GMP Inspectorates EUR 490.- per delegate plus VAT The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

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 22554.

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.

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Organisation and Contact

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

CONCEPT HEIDELBERG

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