ECA Academy
Your GMP/GDP Information Source

Speakers

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Artificial Intelligence (AI) in Visual Inspection

Live Online Training on 11 December 2025

Highlights

- AI in Visual Inspection from a GMP Inspector‘s Perspective
- Project Planning of AI – AVI systems
- Qualification of AI – AVI systems
- Case Study: Usage of AI in the Visual Inspection of hard-to-inspect Items

Programme

Objectives

It is the aim of this event to inform about the possibilities and limitations of Artificial Intelligence in the automated visual inspection of parenterals.

In addition, Good Machine Learning Practices throughout the entire process will be explained and solutions will be presented on how AI projects can be established and validated in a risk-based and traceable manner in the GMP environment.

Background

The pharmaceutical industry is increasingly interested in AI for the visual inspection of parenterals to optimize and enhance process efficacy. However, the lack of specific regulatory requirements for AI validation poses challenges from a Good Manufacturing Practice (GMP) perspective, such as data representativeness, model design, and data integrity throughout the product lifecycle.

In visual inspection, AI aims to improve efficiency by reducing the false acceptance rate (FAR) of defect units and the false reject rate (FRR) of good units, which together determine the misclassification rate and the inspection process‘s effectiveness. A high FAR is associated with a possible quality risk, while the FRR is a measure of the economic damage of the selected control process.

Despite its potential, the FDA‘s guidance on automated systems mentions AI only briefly, highlighting the need for comprehensive regulation and addressing technical challenges like training, domain knowledge, and data quality. Implementing AI systems requires specialized expertise, precise data labelling, and cloud computing for model training.

At this online training, we will be focussing on GMP regula-tion and technical aspects. Questions such as

- What expectations can be placed on the achievable false reject rates of AI-supported inspection systems?
- Are there applications or technical limitations that even AI-supported systems cannot solve?
- How to set up a project for switching to AI-based visual inspection?
- What GMP authority requirements are there for such systems?

will be discussed and possible solutions presented.

Target Audience

The target group for this event are specialists and managers in the pharmaceutical industry from the fields of engineering, production and quality assurance who are involved in the organisation or operation of visual inspection. This training is also aimed at suppliers involved in the development and automation of inspection systems.

Moderator

Felix Krumbein

Programme

Artificial Intelligence (AI) in Visual Inspection from a GMP Inspector‘s Perspective

- Legal basis
- GAMP® and AI (ML)
- Validation
- Operation and raw data

Application, Project Planning and Qualification of AI in fully automated Visual Inspection

- Development of robust, reliable and production-ready models in 4 phases
  - Phase 1: Problem identification & description
  - Phase 2a: Specification of inspection concept
  - Phase 2b: Definition of the sample sets (artificial and production samples), creation of the datasets, clarification of the labelling strategy
  - Phase 3: Model design, training and verification – a risk-based approach
  - Phase 4: Qualification & validation
- Processes & technologies
  - Technologies for efficient image data acquisition, variable model technologies, transfer learning / pre-trained models, labelling application
  - Documentation of model development: traceability, risk minimisation and build-up of confidence

Usage of AI in the Inspection of hard-to-inspect Container-Systems

- Manual, semi-automated and fully-automated approaches
- Use of Artificial Intelligence
- Single chamber and multi-chamber bags
- Inspection of Blow-Fill-Seal containers
- Inspection of Form-Fill-Seal containers
- General approach
- Training and Machine Learning
- Testing and Validation
- Limitations

Speakers

Haluk Dönmez
B. Braun, Germany

Haluk Dönmez has 23 Years work experiences in Life Sciences. His current position is "Head of QM Digital Transformation" in global QM of B.Braun Melsungen AG.

Klaus Feuerhelm
GMP Inspector, RPR Tübingen, Germany

Klaus Feuerhelm is a power plant electronics engineer and pharmacist and has been employed as a GMP inspector at the Tübingen Regional Council since 1996. He is responsible for GMP inspections and manufacturer monitoring. He is a member of the ZLG's Computerised Systems Expert Group.

Felix Krumbein
Head ECA Visual Inspection Group, Germany

Mr Krumbein studied optotechnics and image processing and was head of Inspections-Systems-Support at Roche for many years. From 2022 he headed the Visual Inspection division at InspectifAI. Mr Krumbein is Head of the ECA Visual Inspection Group. Today, he runs his consultancy STIC consulting.

NEWS

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

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „...All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.

This could be of interest for you as well

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)

Live Online Training: Artificial Intelligence (AI) in Visual Inspection
11 December 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)

General terms and conditions
If you cannot attend the conference you have two options:
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- Cancellation until 4 weeks prior to the conference 10 %,
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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 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.

Date of the Live Online Training

Thursday, 11 December, 09.00 to approx. 15.30 h
All times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At https://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 € 990
APIC Members € 1,090
Non-ECA Members € 1,190
EU GMP Inspectorates € 595

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 22427.

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?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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