ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
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Speakers


Ib Alstrup
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B. Braun, Germany


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GMP Inspector,
RPR Tübingen, Germany


Martin Heitmann
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Ulm University Medical Center, Germany

(AI) Artificial Intelligence:
- In a GxP Environment
- In Visual Inspection

Live Online Conferences on 29/30 October 2024 and 31 October 2024

Save up to € 400,- by booking both courses!

Highlights AI in a GxP Environment

- How to apply GxP Regulations to AI (Artificial Intelligence) and ML (Machine Learning)
- What Questions to expect during an Inspection?
- Which Validation Approach is applicable to AL/ML Systems?
- What are typical Risks and Opportunities?
- What are the (current) Limitations of AI/ML Applications?
- Legal Requirements
- Case Studies

Highlights AI in Visual Inspection

- What is AI? – Reality and Opportunities
- 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

(AI) Artificial Intelligence in a GxP Environment

Objectives

Why should you participate in this event?

- You will learn the basics of AI / ML and its applicability in the GxP environment
- How can pharmaceutical basics, e.g. risk management and qualification / validation be applied to AI? You will experience first approaches!
- Are relevant pharmaceutical regulations adapted to this new technology and what expectations does an inspector have during an inspection? First concepts will be presented!
- In case studies, pharmaceutical companies show first practical and practised approaches to the use of AI

Background

At the latest, Artificial Intelligence (AI) has arrived in the general public since ChatGPT and Bard. Opinions range between absolute euphoria and the invocation of the downfall of humanity. The foundations of AI were laid many years ago and can now be widely implemented due to massively available computing power.
The topic has also found its way into the pharmaceutical landscape. First applications have come into operation. The interesting questions here are whether and how this technology is compatible with pharmaceutical regulations, specifications and authorities' expectations.

Target Audience

The Live Online Training is aimed at managers and QA members as well as engineers from the pharmaceutical industry, suppliers and service companies who qualify and operate AI applications in a GxP environment.

Programme

Introduction to Artificial Intelligence (AI)

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

Introduction to Machine Learning (ML)

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

AI in Image Processing

- Introduction to deep learning models for imaging
- Deep learning for diagnosis and prognosis
- Pre-training of deep learning models
- Explainable Artificial Intelligence

AI/ML in Pharma, Biotech, and Med Devices

- Challenges for the Life science industry
- The GAMP-perspective on AI/ML
- Use cases / Known scenarios

Regulatory Requirements / Concerns / Assessment

- Pharmaceutical laws
- EU-GMP Guide Annex 11
- Inspection strategy
- What do inspectors expect from the regulated user?

Inspection Readiness

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

Data and Models

- Overview of model and data types
- Data split: training, validation, testing
- Data quality, representativeness and typical data challenges
- Use of synthetic data

Introduction to and Application of Generative AI in Regulated Pharma

- Introduction to Large Language Models (LLM) and example use cases
- Specialization and tailoring of LLMs in computerized systems
- Typical risks when using LLMs
- Performance evaluation and validation strategies for LLMs

Generative AI - Legal Requirements and practical Implementation

- AI and law: introduction and overview
- Outlook and update on the EU AI Act
- Copyright and trade secrets
- Data protection requirements and processing of personal data
- Practical implementation and best practicess

Validation Approaches

- Maturity: Increasing autonomy and transferring control
- Governance: Developing and operating AI solutions in GxP-regulated areas

The Use of Artificial Intelligence in Pharmaceutical Manufacturing, Developments, Implementation, and Examples

- Risks and Opportunities
- Preparing the Quality Management System for AI
- Where to implement and what to avoid
- Practical examples and attention points
- Validation requirements
- Future Developments

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

Efficiency Increase in Pharma Production Lines through GMP-compliant AI Tools – Case Study Review

- Lessons learned from primary and secondary packaging lines and Auto-Injectors production
- When continuously learning and situationally acting tools can help and when not
- Introduction of Use cases for live learning optimization tools in GMP-environment
- Short Intro: AI-based behavior learning on high frequency machine data of whole production lines
- Obstacles during validation
- Learnings from 24/7-operations integration
- Review of realistic and unrealistic benefits

Trustworthy AI: Innovative Approaches for Transparency in Validation

- Black box or partner: How can transparency of AI be increased?
- Interpretability of AI-based decisions
- Foundations of Explainable AI
- Approaches for the validation of AI systems in GxP environment

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 conference, we will be focussing on GMP regulation and technical aspects. Questions such as

- Does an automatic AI solution eliminate the need for manual visual inspection?
- When does the use of Artificial Intelligence make sense?
- 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 does a project to switch to AI-based visual inspection work?
- What GMP authority requirements are there for such systems?

will be discussed and possible solutions presented.

Target group

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 conference is also aimed at suppliers involved in the development and automation of inspection systems.

Moderator

Felix Krumbein

Programme

Reality & Opportunities of AI in the Industrial Environment

- What is Artificial Intelligence?
- Is GenAI a Game Changer?
- Opportunities and risks
- Industrial Use cases

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

Ib Alstrup
GxP IT Medicines Inspector
Danish Medicines Agency, DKMA, Denmark

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.

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.

Martin Heitmann
d-fine GmbH, Germany

Martin Heitmann works as a senior manager at d-fine Healthcare with a focus on complex process-related and technological transformation projects. Martin Heitmann leads the GAMP D-A-CH Local Special Interest Group on the application of AI in the regulated sector.

Frank-Uwe Hess
Accenture, Germany

Frank-Uwe Hess is a graduate engineer in business economics. He started his career as software developer and consultant. He has been managing director at T.A. Cook for more than 25 years before he joined Accenture in 2021. Today he is managing director & the Global Lead for Intelligent Asset Management at Accenture.

Stefan Hessel
Reusch Rechtsanwaltsgesellschaft, Germany

Salary Partner and Head of Digital Business at Reusch Rechtsanwaltgesellschaft in Saarbrücken.

Felix Krumbein
Head ECA Visual Inspection Group, Germany

Mr. Krumbein studied optotechnics and image processing. He was head of Inspections-Systems-Support at Roche Mannheim, where he was responsible for the qualification of visual inspection systems. He also was Head of Visual Inspection at INSPECTIFAI being responsible for the development of AI-based solutions for fully automated inspection machines. Mr. Krumbein is Head of the ECA Visual Inspection Group.

Speakers Live Online Conferences (cont.)

Felix Georg Müller
plus10 GmbH, Germany

Felix Georg Müller is CEO and Co-founder of plus10 GmbH, which he founded in 2019 together with Pablo Mayer and Thomas Hilzbrich as a high-tech spin-off of Fraunhofer IPA (Fraunhofer is Europe's largest applied research association with more than 72 institutes)

Stefan Münch
Körber Pharma Consulting GmbH, 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.

Urs Alexander Peter
DHC Dr. Herterich & Consultants GmbH, Germany

Urs Alexander Peter is Innovation Consultant at DHC Consulting GmbH. He develops and deploys AI- and ML-based tools in the GxP environment and in accelerating the validation process by automation.

Hendrik Rolshausen
DHC Dr. Herterich & Consultants GmbH, Germany

Hendrik Rolshausen is Consultant IT-Compliance/ CSV at DHC Consulting GmbH. He supports customers in the use of AI- and ML-based tools in the GxP environment and in accelerating the validation process by automation.

Yves Samson
Kereon AG, Basel, 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'.

Jürgen Schmitz
GSK Biologicals, Wavre, Belgium

Juergen Schmitz has nearly 30 year of experience in consulting and in IT for major pharmaceutical companies. He worked for KPMG, Novartis and GSK in different roles leading IT Departments for Quality as well as eCompliance departments and PMOs. Currently he works as Director Quality Transformation Hub, System, Data and eCompliance for GSK Biologicals in Wavre Belgium.

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. He is also investigating methods to achieve good results in medical deep learning even with only little annotated data available.

Organisation and Contact

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

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For questions regarding content of AI in Visual Inspection please contact:
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For questions regarding organisation please contact:
Mr Rouwen Schopka (Organisation Manager) at
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Live Online Conferences

AI in a GxP Environment

☐ *29-30 October 2024*

AI in Visual Inspection

☐ *31 October 2024*

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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.

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Date of the Live Online Conference

(AI) Artificial Intelligence in a GxP Environment
Tuesday, 29 October 2024, 09.00 to approx. 18.00 h
Wednesday, 30 October 2024, 09.00 to approx. 17.00 h

(AI) Artificial Intelligence in Visual Inspection
Thursday, 31 October 2024; 09.00 to approx. 16.30 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)

Fees AI in a GxP Environment
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945

Fees AI in Visual Inspection
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.

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APIC Members € 2,580
Non-ECA Members € 2,680
EU GMP Inspectorates € 1,340

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Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the numbers 21458, 21676, 21786.

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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