ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Haluk Dönmez
B. Braun, Melsungen, Germany

Christophe Girardey
wega Informatik, Basel, Switzerland

Dr Mario Holl
INSPECTIFAI, Karlsruhe, Germany

Julius Kittler
Merck, Darmstadt, Germany

Dr Hadj Latreche
F. Hoffmann-La Roche, Basel, Switzerland

Stefan Münch
Körber Pharma Consulting, Karlsruhe, Germany

Yves Samson
Kereon, Basel, Switzerland

Nicolas Schaltenbrand
Wega Informatik, Basel, Switzerland

Thomas Singer
Merck, Darmstadt, Germany

Dr Arno Terhechte
GMP Inspectorate/ Bezirksregierung Münster, Germany

(AI) Artificial Intelligence in a GxP Environment

With a half-day Pre-Training Course on IT Basics for AI

Live Online Training on 9/10 October 2023

Highlights

- 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?
- Case Studies from:
  - B. Braun
  - F. Hoffmann La-Roche
  - InspectifAI
  - Merck

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: Pre-Training Course on IT Basics for AI

Introduction to Artificial Intelligence (AI)
Stefan Münch / Yves Samson

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

Introduction to Machine Learning (ML)
Stefan Münch / Yves Samson

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

AI/ML in Pharma, Biotech and Med Devices
Stefan Münch / Yves Samson

- Challenges for pharmaceutical industry
- The GAMP-perspective on AI/ML
- GMLP: SDLC for AI/ML
- Use cases / Known scenarios

Data Science as Basis for AI
Nicolas Schaltenbrand & Christophe Girardey

- Pre-requisites for AI: Data Governance, Data Science, Data Understanding, FAIRification
- Specificities in the lab
  - Lack of standardization, Lack of connectivity
  - Chances with standards: AniML, SiLA
- Specificities in clinical development

The Regulatory Landscape for AI/ML
Stefan Münch / Yves Samson

- US / FDA: Expectations and guidance
- EU / EMA: Expectations and guidance
- Special case: Generative AI

Programme: (AI) Artificial Intelligence in a GxP Environment

Regulatory Requirements / Concerns
Dr Arno Terhechte

- Pharmaceutical laws (AMG and other)
- EU-GMP Guide Annex 11
- Concept Paper Revision of Annex 11
- Software as Medical Device

Validation Approaches
Stefan Münch / Yves Samson

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

Risk Management
Stefan Münch / Yves Samson

- Power with control: Explaining the outcomes of trained models
- Applying QRM to development and operation of AI applications

Regulatory Requirements / Assessment
Dr Arno Terhechte

- Inspection strategy
- What do inspectors expect from the regulated user?

Case Study: Predictive Control of Yield & Titer
Dr Hadj Latreche

- Apply Advanced Analytics to enable predictive Titer/Yield and reduce variability while increasing mean toward high-end value
- In-Flight predictive and adaptive process oversight for shop floor to target Titer/Yield Golden Batches
- Prove the value of utilizing Advanced Analytics as a digital product leveraging different data sources and advanced predictive algorithms
- Build site future capabilities required for a sustainable way of working using Advanced Analytics

Case Study: AI in Medical Device Area
Christophe Girardey

- Introduction on the regulations in Medical Device area
- AI in Medical Device:
  - Patient risk: more direct than in Pharma?
  - Reality not future: FDA list of devices released.
- Guidelines on AI:
  - (FDA GMLP > optional as already covered in one of the other sessions)
  - AI & Cybersecurity (ENISA guideline)
  - NMPA Guideline on AI
- Examples of a use case:
  - Electrocardiogram analysis with AI

Case Study: Revolutionizing Visual Inspection with Artificial Intelligence
Dr Mario Holl

- Pain points in visual inspection
- A machine-agnostic AI solution framework
- Strategies for developing robust and reliable AI models
- Qualification and necessary documentation
- Results of AI powered visual inspection

Case Study: Challenges and Limitations of Machine Learning Systems in Automated Visual Inspection Systems
Haluk Dönmez

- Introduction and Basics
- Application and Challenges
- Approach and ML Training
- Testing and Qualification
- Conclusion

Enhancing Production Efficiency: An End-to-End Process Perspective through Data Science
Julius Kittler / Thomas Singer

- Introduction and Overview of the Use Case
- Consolidating the Tablet Production Process into a Comprehensive Dataset
- Theoretical Basics of Machine Learning and Gradient Boosting Decision Trees
- Application of Machine Learning to Identify Critical Factors Impacting Production Target Variables
- Key Takeaways and Lessons Learned

Speakers

Haluk Dönmez, B. Braun AG, Melsungen, Germany
23 Years work experiences in Life Sciences. Current position is “Head of QM Digital Transformation” in global QM of B.Braun Melsungen AG.

Christophe Girardey, wega Informatik AG, Basel, Switzerland
Managing Director and Head of CSV & QA at wega Informatik AG, Basel. He supports customers regarding the best use of agile methodology in GxP environment and as well as projects using AI in GxP/Medical Device. Christophe is also member of the Steering Committee of GAMP Francophone.

Dr Mario Holl, INSPECTIFAI GmbH, Karlsruhe, Germany
Chief Transformation Officer and Chief Digital Officer of Körber Pharma GmbH from 2018 to 2021. Since 2021 Managing Director and VP Product & Relations, InspectifAI GmbH responsible for all commercial topics of InspectifAI.

Julius Kittler, Merck KGaA, Darmstadt, German
Julius Kittler is a Senior Data Scientist at the Data Science & AI team at Merck Healthcare KGaA. He holds a MSc in Statistics and Machine Learning from Linköping University and has been applying his skills at Merck since 2020 in various contexts including R&D, supply chain, and manufacturing.

Dr Hadj Latreche, F. Hoffmann-La Roche AG, Basel, Switzerland
Dr. Hadj Latreche is working for Roche since 2014. From 2017 to 2021, he led a global team in charge of the E2E Supply Chain logistics technologies. Lastly, he moved to Digital Manufacturing where he is leading since 2021 a Global Program deploying advanced analytics as services and as products (applications) for productivity/robustness increase and covering all business drivers of pharma technical operations, such as Titer/Yield, E2E Lead Time/Inventory, RCA/deviations, OEE/NPT.

Stefan Münch, Körber Pharma Consulting GmbH, Karlsruhe, 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.

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'.

Nicolas Schaltenbrand, Wega Informatik AG, Basel, Switzerland

+30 years' experience working in pharmaceutical research institutions and Clinical Research industry (CROs), with a focus on data management, biometrics, statistics, data analytics and clinical operations. Significant experience in the design and deployment of information systems and technologies, with a special emphasis on data management & data analytics solutions in cloud environment.

Thomas Singer, Merck KGaA, Darmstadt, Germany

Thomas Singer, Operations & Process Excellence Manager, is responsible for efficiency projects in the bulk manufacturing site Darmstadt of the Merck Healthcare KGaA. Before joining Merck in 2019 he gained experiences in development, simulation and production environments in the steel business and within consulting projects

Dr Arno Terhechte, GMP inspectorate / Bezirksregierung Münster, Germany

After 5 years in the pharmaceutical industry he was from 1998 – 2003 in the 'Bezirksregierung Düsseldorf'. Since 2003 he is inspector in the 'Bezirksregierung Münster'. Arno Terhechte is chairman of the German expert group 11 "computerised systems"'.

Date of the Live Online Training

Pre-Training Course on IT Basics for AI
Monday, 9 October 2023, 13.00 – 18.00 h

(AI) Artificial Intelligence in a GxP Environment
Tuesday, 10 October 2023, 09.00 – 18.00 h
All times mentioned are CEST

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 pre-Training Course (per delegate, plus VAT)

ECA Members € 590.-
APIC Members € 640.-
Non-ECA Members € 690.-
EU GMP Inspectorates € 395.-
The conference fee is payable in advance after receipt of invoice.

Fees (AI) Artificial Intelligence in a GxP Environment (per delegate, plus VAT)

ECA Members € 1090.-
APIC Members € 1140.-
Non-ECA Members € 1190.-
EU GMP Inspectorates € 595.-
The conference fee is payable in advance after receipt of invoice.

Fees Combi (per delegate, plus VAT)

ECA Members EUR 1490.-
APIC Members EUR 1590.-
Non-ECA Members EUR 1690.-
EU GMP Inspectorates EUR 990.-
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org

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 Live Online Training.
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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 Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. **This training course is the first element for your additional certification.** Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Live Online Training:

☐ (AI) Artificial Intelligence in a GxP Environment, 10 October 2023
☐ Pre-Training Course on IT Basics for AI, 9 October 2023

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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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.

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