Digitalisation & Artificial Intelligence

Part of PharmaCongress 2024

19/20 March 2024
Wiesbaden, Germany

Highlights

- How Digitalisation and Artificial Intelligence increases pharmaceutical Efficiency and Quality
- Are there specific Requirements from the supervisory Authorities; which Points must be observed?
- Case studies from:
  - Boehringer Ingelheim International
  - F. Hoffmann-La Roche
  - Pharmathen
  - Roche Diagnostics
  - Sanofi-Aventis
  - Sartorius Stedim

Speakers

Ib Alstrup | Danish Medicines Agency

Yvonne Duckworth | CRB, USA

Dr Armin Hauk | Sartorius Stedim Biotech, Germany

Martin Heitmann | d-fine, Germany

Dr Ulrich Köllisch | GxP-CC, Germany

Dr Tobias Ladner | Roche Diagnostics, Germany

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

Galit Lisaey | Gal.IT Data Integrity Consulting, Israel

Dr Jean-Denis Mallet | Pharmaplan, Former head of the French Inspection Department AFSSAPS

Dr Sven Alexander Moritz | Sanofi-Aventis Deutschland, Germany

Stefan Münch | Körber Pharma Consulting, Germany

Dr Daniel Samson | Bachem, Switzerland

Yves Samson | Kereon , Switzerland

Dr Jörg Stüben | Boehringer Ingelheim International, Germany

Ioannis Tsiagkas | Pharmathen, Greece

ECA Academy
Your GMP/GDP Information Source

GMP-PHARMA CONGRESS

This conference is part of PharmaCongress 2024

GMP–PHARMA CONGRESS

DIGITALISATION & ARTIFICIAL INTELLIGENCE

OBJECTIVES

Reasons to attend this conference:

- You will get an overview of current digitalisation and artificial intelligence in the pharmaceutical industry.
- You will learn how efficiency and quality can be improved through the implementation of digitalisation.
- In various case studies of pharmaceutical companies, projects from practice are presented.

BACKGROUND

New forms of digitalisation are finding their way more and more into the pharmaceutical industry. If the automation stage is already well advanced, topics such as AI, IOT and Industry 4.0 are waiting in the wings. Artificial Intelligence has arrived in the general public since Chat GPT and Bard, but has also found its way into the pharmaceutical industry.

Therefore, the track will primarily be dedicated to Artificial Intelligence and present and discuss initial experience from established projects. The focus will be on GxP-relevant aspects from the perspective of the pharmaceutical industry and the regulatory authorities.

TARGET AUDIENCE

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with digitalisation and AI projects. It particularly addresses the departments IT, Production, Quality Assurance and Engineering / Technology.

MODERATORS

Stefan Münch, *Körber Pharma Consulting*
Yves Samson, *Kereon*

PROGRAMME 19 March 2024

An Overview on AI/ML in GxP Environments

Stefan Münch, *Körber Pharma Consulting*
Yves Samson, *Kereon*

- Basics of AI/ML
- AI/ML along the pharmaceutical value chain
- Promising use cases in pharma manufacturing
- Regulatory challenges of AI/ML in GxP
- Risks and Controls of AI/ML in GxP

Regulatory Requirements and Inspector's View on Artificial Intelligence

Ib Alstrup, *Danish Medicines Agency, DMA*

Use of AI in daily Deviation and CAPA Management

Dr Sven Alexander Moritz, *Sanofi-Aventis Deutschland*

- Use of AI to discover early signals in deviation trending
- Shorten investigation time
- Improve CAPA definition and implementation based on real life data

Validation of AI/ML in the GxP Environment

Dr Ulrich Köllisch, *GxP-CC*

- Regulatory overview: What are the new guidelines, best industry practices and discussion papers on AI/ML validation (EMA, FDA)
- Prerequisites for AI/ML validation (Data Governance) and the AI/ML model Lifecycle
- Two case studies: High Level Risk Assessment for NLP implementation in the QMS and for visual inspection; Application of ICHQ9 (R1) with a patient-centric mindset
- Conclusion and Outlook: An industry overview of the current status and what is to be expected next

When Data runs wild – Data Integrity as a Control Tool for AI

Galit Lisaey, *Gal.IT Data Integrity Consulting*

- The Importance of Data Integrity in Decision-Making
- Challenges: Transition to Automated Systems
- Data Integrity as an Organizational Interest
- Risks and Reliability in AI-Based System
- Immediate Solutions: Regulatory Tools and Methodologies

Enabling ML Applications by a "Data Expert Team"

Dr Jörg Stüben, *Boehringer Ingelheim International*
Martin Heitmann, *d-fine*

- Relevance of data in ML enabled applications
  - The Subject Matter Expert's view: Searching for the right use case
  - The Data Scientist's view: Searching for the right method
  - Reaching the common goal: The „Data Expert Team" featuring insights from real world examples

PROGRAMME 20 March 2024

Applying Industry 4.0 – What are the Use Cases and how can they be successfully implemented

Dr Daniel Samson, *Bachem*
Yvonne Duckworth, *CRB*

- The pharma industry is ready to move into the digital age and hungry for 4.0 advancements, but decision-makers are still unsure where and how to apply these technologies
- The speakers examine Pharma's use of Industry 4.0 from three angles: the owner, the service provider, and the governance
- Get an overview and examples of Industry 4.0 concepts along typical manufacturing processes within BACHEM AG
- Learn how the AEC industry is incorporating 4.0 into pharma facilities

How the Digital Transformation could really improve Inspections & Audits Effectiveness and Efficiency

Dr Jean-Denis Mallet, *Former head of the French Inspection Department AFSSAPS, Pharmaplan*

- What e-technologies could add to the desired transparency of the inspection / audit process
- How confidence can be built through the e-technological approach
- Is 'AI' a Dr Jekyll approach or a Mr Hyde too?
- Conclusion: how to help 'AI' in the inspection / audit process

Quality Contracts in the Era of Digitalisation and AI

Ioannis Tsiagkas, *Pharmathen*

- Digitalisation and AI can be utilized within pharmaceutical quality contracts to improve efficiency, accuracy, and compliance
- Document Management: AI-powered document management systems
- Supplier Quality Management: AI can assist in evaluating and monitoring the quality performance of suppliers involved in pharmaceutical manufacturing
- Compliance Monitoring: AI systems can detect deviations from contractual obligations and regulatory standards, providing real-time alerts and facilitating corrective actions
- Real-time Quality Monitoring: AI-powered monitoring systems can continuously collect and analyze data from various sources

Bridging Innovation and Compliance: Open-Sourcing Data Computation Platform (DCP) for GxP-Compliant Pharma 4.0 Advancements

Dr Tobias Ladner, *Roche Diagnostics*

- Introducing Data Computation Platform (DCP): Enabling GxP-Compliant Advancements and Supporting Tools in One Platform
- Validation: Ensuring GxP Compliance and Reliability of the Data Computation Platform (DCP)
- Use Case: Leveraging DCP for GxP-Compliant Multivariate Data Analytics Process Monitoring
- Journey Towards Open-Sourcing: Overcoming Challenges and Fostering Collective Progress

Predictive Control of Titer/Yield & Quality for Biomanufacturing

Dr Hadj Latreche, *F. Hoffmann-La Roche*

- Apply Advanced Analytics to enable predictive Titer/Yield & Quality and reduce variability while increasing throughput and quality robustness in a GMP environment
- In-Flight predictive and adaptive process oversight for shop floor to target Titer/Yield & Quality 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

Simplified Extractables and Leachables Assessment using prior Knowledge and IT Solutions

Dr Armin Hauk, *Sartorius Stedim Biotech*

- Prediction of extractables profiles for SU devices of different sizes and complex assemblies
- Calculation of exposure data, with a subsequent automated safety-assessment; including a discussion of deviations and propagation of deviations
- Equivalency study of extractables profiles of a SU assembly before and after a component change, including the evaluation of the impact on the safety assessment
- Using the system to extrapolate extractables data to USP <665> conditions for a safety assessment of a large volume injectable drug product

SPEAKERS

Ib Alstrup
Danish Medicines Agency, DMA, Copenhagen, 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.

Yvonne Duckworth
CRB, Conshohocken, USA
Yvonne is a registered automation engineer with 30 years of technical design and project leadership experience within the pharmaceutical and biotech industries. She serves as a chairperson on the ISPE Pharma 4.0™ Leadership Team, a member of ISPE, Women in Pharma, Women in Bio, and ISA.

Dr Armin Hauk
Sartorius Stedim Biotech GmbH, Göttingen, Germany
After his PhD in 1995, Armin joined the central analytical department of Ciba-Geigy Inc., amongst others with focus on E&L investigations. From 2010 on Armin was active as consultant mainly in the area of E&L for Intertek in Basel. Since June 2016 Armin has a position at Sartorius-Stedim Biotech as Principle Scientist E&L.

Martin Heitmann
d-fine GmbH, Frankfurt, Germany
Martin started his career 2016 in the financial services area. Having been involved in various projects around big data and predictive analytics topics, he then moved to the d-fine Healthcare practice supporting clients on their digital transformation path. Martin leads the GAMP D-A-CH Special Interest Group (SIG) AI and is author at the ISPE Pharmaceutical Engineering.

Dr Ulrich Köllisch
GxP-CC GmbH, Kaiserslautern, Germany
Ulrich Koellisch is an experienced speaker and trainer in the area of Data Integrity, Digital Compliance and Quality Risk Management, supporting industry affiliations (DI Interest Group leader with PDA) and serving as a trainer of regulatory bodies for the ICH. Ulrich has about nine years of hands-on consulting experience in the pharmaceutical industry.

Dr Tobias Ladner
Roche Diagnostics GmbH, Mannheim, Germany
Tobias Ladner pioneered the Data Computation Platform (DCP) concept, with over six years to forge innovative pathways within the manufacturing network. Leading a dynamic team, he oversees the global rollout, operations, and evolution of DCP and related global business processes, catalyzing transformative change.

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.

Galit Lisaey
Gal.IT Data Integrity Consulting, Givat Ada, Israel
Galit Lisaey, Director and Founder of Gal.IT Data Integrity Consulting, transitioned to consulting five years ago after over 20 years in computerized system management roles. She holds a Master of Science degree and has worked as an immunologist and method development researcher in various R&D institutes and pharmaceutical departments.

Dr Jean-Denis Mallet
Pharmaplan
He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). Now he is member of the ECA advisory board and works for NNE Pharmaplan.

Dr Sven Alexander Moritz
Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany
Pharmacist, with Ph.D. in Molecular Biology with >15 years experience in Manufacturing (API, Fill & Finish) as well as Quality (Quality systems).

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.

Dr Daniel Samson
Bachem AG, Bubendorf, Switzerland
Since 2012, he has held the position of Vice President of API Manufacturing, taking full charge of large-scale solid-phase peptide and oligonucleotide syntheses, downstream operations, and CMC activities within Bachem AG.

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'.

Dr Jörg Stüben
Boehringer Ingelheim International GmbH, Ingelheim, 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.

Ioannis Tsiagkas
Pharmathen S.A., Pallini, Attica, Greece
Pharmaceutical quality professional with more than 10 years exposure to all aspects of corporate pharma quality and extensive experience in contracts negotiation; he has 20 years of accumulated experience in life sciences and biotech products.

The guiding theme of the GMP PharmaCongress 2024 on 19/20 March will be „users sharing challenges and solutions in practice". Therefore, benefit from your colleagues' experience and from the direct information exchange at the GMP PharmaCongress & GMP PharmaTechnica 2024.

The Conference Tracks

As a participant you can switch between any of the **11 conference tracks** any time and also visit the PharmaTechnica Expo with more than 110 international exhibitors.

The GMP PharmaCongress Conference Tracks	19 March 2024	20 March 2024
Non-Sterile Products – Challenges in Manufacturing & Quality	✓	n.a.
GMP – Green or Good Manufacturing Practice?	✓	n.a.
Packaging/Packaging Materials – Challenges & Solutions	n.a.	✓
European Aseptic Conference – Technology	✓	✓
Trends in Barrier Systems & Robotics	✓	✓
Modern Cleanroom Technology	✓	✓
Digitalisation & Artificial Intelligence	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Lyophilization – Modern Techniques & New Requirements	✓	✓
ATMPs – Hurdles & Achievements in Quality and Safety	✓	✓
Vaccines – Advantages & Challenges in Manufacturing	✓	✓
GMP PharmaTechnica Expo	✓	✓

Keynote on 19 March 2024

The CEPI Project – 40 Countries – 1 Billion Euros for Vaccines

Dr Guido Dietrich, *CEPI*

Do you know the worldwide importance of CEPI? And why is this so important for everyone working in pharmaceutical production?
Our first keynote will address a very important new development. More than 40 countries, several non-governmental organizations and the European Commission are involved in the **Coalition for Epidemic Preparedness Innovations (CEPI)**.

What is the goal?
The goal of CEPI is to develop, produce and distribute a vaccine as quickly as possible in the event of the next global pandemic, i.e. within 100 days.

What is the current budget?
For the first 5 years alone, a budget of one billion euros has been made available.

In the Live Demo Area in the PharmaTechnica Expo hall you will benefit from the exhibitors' demonstrations – presenting their latest technology, products and services. Take advantage of these live performances – and get to feel and experience their products. For a list of all companies exhibiting at PharmaTechnica, please see the exhibitor list and plan on the website at **www.pharma-congress.com**.

Exhibitor	Stand	Live Demo
boTec	A 7	TBN
MKVersuchsanlagen	A 12	TBN
Ellab	A 16	TBN
Bausch+Ströbel	A 33	OMNIA - Boost your processes and step closer to your pharmaceutical plant of the future.
PHARMAPLAN	A 37	Accelerated Design Decisions enabled by Digital Twins
Quascenta Pte	B 6	Using an Intelligent Lifecycle-Based Solution for Streamlined Product Tracking, Design Optimization, Collaboration, and Reporting
ZETA	B 12	TBN
IWT / Tecniplast	B 15	High pressure cleaning in pharmaceutical production. Advantages, challenges, sustainability and savings
MBV	B 20	TBN
Emerson Automation Solutions	B 22	TBN
Atec Steritec	B 28	Safe & Sterile Transfer with Minimal Operator Intervention
REA Elektronik	B 29	Experts in Printing and Code Verification of pharmaceutical and medical-device packaging (f.e.UDI/MDR)
Friedrich Sailer	B 31	Shining Solutions: Live Demo of Cutting-Edge Stainless Steel Cleanroom Equipment
Merck	B 32	Annex 1's "Specific Risks Associated with Single-Use Systems"
Particle Measuring Systems	C 7	Facility Monitoring Systems
Yokogawa	C 9	Flow Imaging using FlowCam for High Performance Products to warrant constant excellent Quality

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Registration Form:
(06221) 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

Congress Dates
Tuesday, 19 March 2024, 09.00 - 18.00 h
Wednesday 20 March 2024, 09.00 - 17.00 h
Registration
Tuesday & Wednesday, 19/20 March 2024, 08.00 - 09.00 h

Fees
The one day ticket is available for € 690,- plus VAT, both days for € 1,380.- plus VAT. It includes participation in any track on that day and the visit of the PharmaTechnica Expo. In addition, lunch and beverages during the tracks and in breaks as well as the social event on the evening of the first congress day, 19 March is included; please mark if you would like to attend the Social Event. The fee is payable in advance after receipt of invoice.

Venue
RheinMain CongressCenter (rmcc)
Friedrich-Ebert-Allee 1 | 65189 Wiesbaden
Phone: +49 (0) 611 1729-444
E-Mail: veranstaltungsservice-rmcc@wicm.de

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms close to the CongressCenter. You will receive a room reservation form 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 message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. 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
P.O.Box 10 17 64
69007 Heidelberg, Germany
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Dr Andreas Mangel (Operations Director) at
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Mr Ronny Strohwald (Organisation Manager) at
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Reservation Form (Please complete in full)

Digitalisation & Artificial Intelligence

Part of PharmaCongress 2024

19/20 March 2024, Wiesbaden, Germany

☐ Day 1 & 2 (19/20 March 2024)
☐ Day 1 (19 March 2024)
☐ Day 2 (20 March 2024)

☐ Yes, I would also like to take part in the Social Event on the evening of 19 March 2024.

☐ Mr ☐ Ms ☐ Mx ☐ Dr

First name, Surname

Company

Department

Important: Please indicate your company's VAT ID Number P.O. Number (if applicable)

Street/P.O. Box

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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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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/eca_privacy.html). 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.

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