

Speakers



Oliver Bosch
Epista Life Science
Deutschland



Thorsten Haefner
PSM



Eva Kelly
ERA Sciences



Anja Koeleman
Vetter Pharma-Fertigung



Christopf Köth
Fresenius Kabi Austria



Stefan Münch
Körber Pharma
Consulting



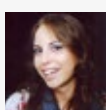
Milos Nikolic
Galenika



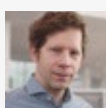
Marick Paris-Cadet
Technip Energies



Julian Petersen
groninger & co.



Ana Cláudia Pinho
BIAL - Portela & C.^a



Marco Reiss
Paul Ehrlich Institut



Yves Samson
Kereon



Jürgen Schmitz
GSK Biologicals



Dr. Arno Terhechte
GMP Inspectorate

Pharma 4.0 & Digitalisation

Part of PharmaCongress 2023

28/29 March 2023 | Wiesbaden, Germany



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Highlights

- How digitalisation increases pharmaceutical efficiency and quality
- Are there specific requirements from the supervisory authorities; which points must be observed?
- Case studies from:
 - BIAL
 - Fresenius Kabi Austria
 - Galenika
 - GSK Biologicals
 - PSM
 - Technip Energies
 - Vetter Pharma-Fertigung



This conference is part of PharmaCongress 2023

Objectives

Reasons to attend this conference:

- You will get an overview of current digitalisation trends 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.

The conference will address these topics 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 projects.

It particularly addresses the departments:

- IT
- Production
- Quality assurance
- Engineering / Technology

Moderators

Yves Samson

Kereon AG, ECA DI&IT Compliance Interest Group

Stefan Münch

Körber Pharma Consulting, ECA DI&IT Compliance Interest Group

Congress Keynotes

28 March 2023

Comprehensive Transformation of DR. KADE's Sites and Supply Chain

Dr Norbert Marquardt, Dr Kade Health Care

29 March 2023

Trends in Aseptic Manufacturing: Questions and demands for Pharma Machine Vendors

Dr Friedrich Haefe, formerly Boehringer Ingelheim Pharma

Programme

Introduction: Digitalisation in GxP Environment: Between Mantra and Reality

Yves Samson, Kereon

Stefan Münch, Körber Pharma Consulting

- Inhibitors
- Triggers
- Enablers
- Pitfalls

Digitalisation from the Inspector's Point of View

Dr Arno Terhechte, GMP Inspectorate / Bezirksregierung Münster, Germany

Influence of Digitalisation on the Future Work of Quality Departments

Jürgen Schmitz, GSK Biologicals

- From Paper to Data
- Critical thinking
- Review by exception
- From control to continuous improvement to Digital Twin
- Validation today and tomorrow
- What will change for Quality?

Live Demos

Vial Inspection: Classical Machine Vision vs. Deep Learning

OCTUM

- Empty vial inspection for contamination and glass defects
- Inspection with machine vision: classical rule-based approach compared with deep learning
- Showing both solutions simultaneously
- Complying with 21 CFR Part 11 and EU-GMP

Accelerated Design Decisions Enabled by Digital Twins

Pharmaplan

- Pharmaplan's Process & Laboratory Equipment BIM (Building Information Modeling) & CAE (Computer Aided Engineering) Library
- Integrated Pharmaplan Engineering Database
- VR & AR Applications

EMSuite® - Monitoring Next Generation

Ellab

- Cloud, SaaS, On Premise installation Digital
- Smart Sensor technology
- Smart layout view
- Action Cards for alert acknowledgement

Case Study – Digitalisation for Construction Management of Large Biopharmaceutical Plant

Marick Paris-Cadet, Technip Energies

- Case study: on-going construction site for a large biotech project localized in north of France, > 500M€ investment
- Coordination between client, engineering company, multiple subcontractors (60+)
- Methodology & Digital tools used for studies management and construction management
 - Collaborative BIM for 3D model, synthesis activity
 - Construction workflow/schedule, digital solution for on-site supervision for construction, inspection...
- Feedback & Added value
- Way forward: road map to full digitalisation, virtual reality/augmented reality

Automated Validation – Enabling Better Data Reliability and Integrity in Life Sciences

Eva Kelly, ERA Sciences

- System agnostic presentation discusses the increased use of automated validation solutions
- Reduction in manual transcription Errors
- Centralized management of validation documents and records
- Effort Commensurate with risk – ability to leverage unscripted, scripted and exploratory testing
- Configuration to address True Copy Record concerns

Advanced Monitoring of Production Process Using IIoT System

Milis Nikolic, Galenika

- Current challenges with efficiency and monitoring production process
- Identifying critical points in the process
- How IIoT systems can help
- System Demonstration

Digitalisation and Automation: How to Avoid Losing from Day One, Preventing Successful Transformation to Fall Short

Ana Cláudia Pinho, BIAL - Portela & C.^a

Many transformations are addressed as Digital Transformations instead of business transformations.

- Planning transformation
- Rethink processes
- Use automation to avoid inefficient use of resources

Implementation of Pharma 4.0 at the German CDMO PSM GmbH

Thorsten Haefner, PSM

Julian Petersen, groninger & co.

- Complete paperless pharmaceutical production
- Generation of real-time data for faster batch releases
- Use of virtual twins for higher productivity
- Use of robotics for better process monitoring
- Elimination of humans for repetitive and critical process steps

Are Digitalisation and Artificial Intelligence a Double-Edged Sword in Pharma and Healthcare?

Marco Reiss, Paul-Ehrlich-Institut

- What is really meant with digitalisation and AI in pharma and healthcare?
- New perspectives and chances of digitalisation and AI in a hyperconnected pharma and healthcare sector
- Impact and (potential) risks of further digitalisation on the field of pharma and healthcare
- Do we need a guiding framework? – Critical reflections, overthinking

AI Supported Intervention Detection and Classification in the Aseptic Core

Christoph Köth, Fresenius Kabi Austria

- FrEDIS - Fresenius Event Detection Information System is a pilot system live in routine production which in the current setting allows the detection and classification of human interventions in the aseptic core.
- The development of such a system not only lead to new insights into aseptic manufacturing but also required an innovative (XAI based) approach to better understand AI decisions. This approach also enables a GMP validation where AI no longer acts as a black box.
- Depending on the project progress results of discussions with relevant authorities should be available at the date of the conference.

CASE EVENT with Vetter Pharma-Fertigung – Moving Quality Documents to the Cloud

Anja Koeleman, Vetter Pharma-Fertigung

Oliver Bosch, Epista Life Science Deutschland

- Needs analysis and system selection
- Process optimization
- Validation
- Organisational Change Management

Speakers



Oliver Bosch
Epista Life Science Deutschland

Project Manager and Department Leader with interpersonal skills having a wide background in regulated processes and information technologies within the life science industry with more than 10 years experience.



Thorsten Haefner
PSM
VP Business Development



Eva Kelly
ERA Sciences

Eva has a degree in Analytical Science, PhD in Chemistry and has worked in Life Sciences for nearly 30 years.



Anja Koeleman
Vetter Pharma-Fertigung

After completing her bachelor's and master's degree in business informatics, Anja Koeleman has been working as an in-house digitalisation consultant for ECM Veeva and IT project manager at Vetter Pharma.



Christopf Köth
Fresenius Kabi Austria

Background in IT, chemical engineering and business. Several leading positions (Head QA, Head Production, ..) mainly related to aseptic and highly active products.



Stefan Münch
Körber Pharma Consulting

Stefan Münch, Business Director Validation, is responsible for all validation services of Körber Pharma Consulting.



Milos Nikolic
Galenika

IT professional with over 20 years of experience in multinational companies working on digital, innovation and business transformation by applying cutting-edge IT technologies.



Marick Paris-Cadet
Technip Energies

With 10 years experiences at Technip Energies in Life Sciences, she worked on various pharma projects within three main areas: Project Engineering / Technical coordination, Process & Equipment studies, Commissioning & Qualification. Marick holds a Master's degree in Chemical Engineering (ENSIACET, Toulouse, France).



Julian Petersen
groninger & co.

After a short timeout in the semiconductor/metrology business Julian returned to the pharmaceutical fill&finish business as a Sales Director responsible for the DACH market. Now leading the Business Development and Product management.



Ana Cláudia Pinho
BIAL - Portela & C.^a

Having a master in Chemical Engineering and a post-graduation in Corporate Management, Ana has been working in industry management, especially in process and quality management, strategic planning and management control, developing general analytical and conceptual skills.



Marco Reiss
Paul Ehrlich Institut

Head of Unit Controlling, Quality Management / Deputy head of unit of Press, Information, 20 years of professional experience in the healthcare sector, working as an Economist and MBA at executive level within one of the most renowned regulatory medicinal agencies.



Yves Samson
Kereon AG

Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. He is part of the Board of Directors of the ECA DI&IT Compliance Interest Group.



Jürgen Schmitz
GSK Biologicals

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.



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 member of the German expert group 11 “computerised systems”.

PharmaCongress 2023



The guiding theme of the PharmaCongress 2023 on 28/29 March will be „users sharing challenges and solutions in practice“. Therefore, benefit from your colleagues' experience and from the direct information exchange at PharmaCongress & PharmaTechnica 2023.

The Tracks

As a participant you can switch between any of the tracks any time and also visit the PharmaTechnica Expo with more than 100 international exhibitors.

Conference Tracks	28 Mar	29 Mar
European Aseptic Conference	✓	✓
New Developments in Barrier Systems & Robotics	✓	✓
PUPSIT: Complying with the Main Annex 1 Changes	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Pharma 4.0 & Digitalisation	✓	✓
Handling of Highly Active Products	✓	✓
ATMP – Manufacturing, Quality& Safety	✓	✓
PharmaTechnica Expo	✓	✓

Find out more about the other conference tracks on our website www.pharma-congress.com.

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

Pharma 4.0 & Digitalisation - Part of PharmaCongress 2023, 28/29 March 2023, Wiesbaden, Germany

- ☐ Day 1 & 2 (28/29 March 2023)
- ☐ Day 1 (28 March 2023)
- ☐ Day 2 (29 March 2023)
- ☐ Yes, I would also like to take part in the Social Event on the evening of 28 March 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)

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D-69007 Heidelberg
GERMANY

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 3 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.

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.

Date of the Conference

Tuesday, 28 March 2023, 09.00 - 18.00 h
Wednesday, 29 March 2023, 09.00 - 17.00 h
Registration: 28/29 March 2023, 08.00 - 09.00 h

Venue

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

Fees (per delegate, plus VAT)

The one day ticket is available for € 690,- plus VAT (until 31 January 2023 only € 590,- plus VAT), both days for € 1,380 plus VAT (until 31 January 2023 only € 1,180 plus VAT). It includes participation in any conference track of PharmaCongress 2023 on that day(s) 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, 28 March is included; please mark if you would like to attend the Social Event.

The fee is payable in advance after receipt of invoice.

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.
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