Early Bird Rebate until 31 December:
One Day Ticket 590,- € instead 690,- €

2019 PHARMA CONGRESS
Production & Technology
DÜSSELDORF, 9 - 10 APRIL 2019

Pharma Congress
Production & Technology

Düsseldorf/Neuss, 9/10 April 2019

With the Speakers:


Ib Alstrup
Danish Medicines Agency
Medicines Inspector


Dr Abdulaziz Awad
Saudi Biotechnology Manufacturing Company
Board Member & CEO


Klaus Eichmüller
Wolnzach, c/o Regional Council Darmstadt
Head of Inspectorate


Sandrine Favre
Octapharma
Head Corporate Pharmaceutical Production


Dr Friedrich Haefele
Boehringer Ingelheim Pharma
VP BP Fill & Finish Germany


Philip Hörsch
Vetter Pharma-Fertigung
Director QA


Dr Gerald Kindermann
F. Hoffmann la-Roche
QA and GMP Compliance Lead


Dr Daniel Müller
Local Authority of Baden-Württemberg
Head of GMP Inspectorate


Thomas Page
Fujifilm Diosynth Biotechnologies
VP, Engineering & Asset Development


Gabriela Schallmeiner
Austrian QP Association
Deputy Chair


Arno Terhechte
Regional Council Münster
GMP Inspector

and many others

CONCEPT HEIDELBERG

Pharmaceutical Quality
Training. Conferences. Services.

Overview

Benefit from your colleagues' experience and from the direct information exchange at the Pharma Congress 2019 again – the guiding theme on 9/10 April 2019 will be once more "users report for users". And as before speakers will report about the challenges in their everyday business and about possible solution approaches. So, choose from presentations in five conferences.

Key Notes

Pharma-Kongress – Overview

Key Note 9 April

Pharmaceutical industry in digital change
Thomas Reiner, *CEO, Berndt+Partner*

- Changes in the value chains
- Opportunities and risks for production processes
- What can and will change for packaging?
- Strategies to benefit from change

Key Note 10 April

EU GMP Inspection in Sterile/Aseptic Production
Klaus Eichmüller, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany*
Head of Inspectorate

- Main focus areas of inspections
- Frequently detected findings
- Data Integrity issues – where are possible weak spots?
- Possible new areas due to the revision of Annex 1 and further regulatory changes

Conferences — One Day Ticket € 690,-	9 April 9:00–17:45 h	10 April 9:00–17:00 h
ECA – Modern Sterile Operations		
100% Control of Parenterals	✓	
Sterile Filtration		✓
ECA – Aseptic Processing		
Current Aseptic Terchnologies	✓	
RABS & Isolators		✓
ECA – Data Integrity		
Data Integrity	✓	✓
Exhibition PharmaTechnica	✓	✓

Steering Committee

Dr Friedrich Haefele
Boehringer Ingelheim
Vice President BP Fill & Finish Germany

Dr Rainer Schmidt
F.Hoffmann-La Roche
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Roland Szymoniak
Sanofi
Manager Industrial Engineering & Transfer

Gert Moelgaard
ECA Validation Interest Group
Consultant, Moelgaard Consulting

Frank Studt
Chemgineering Business Design
Managing Director

Günter Körblein
Tetragon Consulting
Senior Consultant

Exhibition

Parallel to the conferences on 9 and 10 April there will be the large exhibition PharmaTechnica. Take advantage of this opportunity to get to know new technologies, products and services at the stands of the exhibitors. For that purpose there will be Live Demos integrated in some of the conferences again. These Live Demos will be conducted in the exhibition area. That way you will not only be introduced to technology in the conferences, but you will be able to touch and experience it. Get to know new concepts and technology – directly from leading companies. You will find the Live Demos in this programme under the respective conferences as well as on the Congress Website at www.pharma-congress.com. There you will also find the daily updated exhibitor list.

Fees

Charges for the one day tickets are € 690,- plus VAT (due to the special fees for the congress, ECA membership discounts are not applicable). These tickets allow you to attend any conference offered that day (you can also switch between the conferences any time). They include a lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day. Charges are payable after receipt of invoice. *(Please also see the information below)*

Location

Crowne Plaza (former Swissôtel) Congress Centrum Düsseldorf / Neuss
Rheinallee 1
41460 Neuss
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
emailus.neu02@gchhotelgroup.com

Social Event

The Social Event at the Pharma Congress is already a tradition, and is networking and relaxation at the same time.

On the evening of the first congress day, on 9 April 2019, all congress delegates and speakers are invited to a „Get together" in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

Contacts

For questions regarding content:
ECA Modern Sterile Operations – 100% Control of Parenterals:
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ECA Modern Sterile Operations – Sterile Filtration / ECA Aseptic Processing / ECA Data Integrity:
Dr Andreas Mangel (Fachbereichsleiter), Tel. +49 (0)6221/84 44 41,
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For questions regarding reservation, hotel, organisation, exhibition etc.:
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PLEASE NOTE

Exhibition Visit: The exhibition will also be open to visitors on both days who are not attending the Congress. Please be aware, though, that you will need to register in advance of the free of charge visit. The visitor registration will most likely be available on the website starting in early April 2019. The visit of the exhibition does not entitle you to also attend any of the conferences.

Congress Materials: Please note that there will not be any print-outs at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Room Reservations: There will be no room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

With speakers from authorities and Industry (as of December 2018)

Ib Alstrup	**Danish Medicines Agency** Medicines Inspector.
Gabriel Anderson	**Novartis** Co-lead Novartis's visual inspection expert network.
Dr Abdulaziz Awad	**Saudi Biotechnology Manufacturing Company** Board Member and CEO.
Stefan Bieler	**IDT-Biologika** Process engineer at IDT-Biologika, Department Filling and Freeze Drying Vaccines.
Klaus Eichmüller	**Wolznach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany** Head of Inspectorate.
Sandrine Favre	**Octapharma** Head of Corporate Pharmaceutical Production.
Dr Friedrich Haefele	**Boehringer Ingelheim Pharma** Head of the department Biopharma Fill & Finish Germany.
Dr Martin Haerer	**Rommelag CMO** Responsible for Business Development, Technology Transfer and Research and Development, and acting as QP.
Philip Hörsch	**Vetter Pharma Fertigung** Director QA - Validation/Risk Management/Trending.
Dr Matthias Kahl	**Wilco** Head of Development and Lab Service.
Dr Gerald Kindermann	**F. Hoffmann La-Roche** QA and GMP Compliance Lead.
Felix Krumbein	**Roche Diagnostics** Head of Inspections-Systems-Support.
Dr Thomas Meindl	**Labor LS** Division Manager.
Didier Meyer	**DMCompliance** Consultant at DMCompliance.
Gerd Moelgaard	**ECA Validation Interest Group** Moelgaard Consulting.
Dr Daniel Müller	**Local Authority of Baden-Württemberg** Head of GMP Inspectorate.
Thomas Page	**FUJIFILM Diosynth Biotechnologies** Vice President, Engineering & Asset Development.
Thomas Reiner	**Berndt+Partner** CEO; Board Member World Packaging Organisation.
Doris Rottenbusch	**Vetter Pharma-Fertigung** Leading a team of experts in Development Service - Technology & Process Transfer.
Knud Ryhl	**Novo Nordisk** Senior Lead Auditor / Senior Specialist.
Prof Farshid Sadeghipour	**Lausanne University Hospital** Head of Pharmacy.

With speakers from authorities and Industry (as of December 2018)

Yves Samson	**ECA DI & IT Compliance Interest Group** Kereon AG, CEO & e-Compliance SME.
Matthias Schaar	**Novartis Pharma, Stein** Teamleader Qualification & Infrastructure in Microbiological Department.
Gabriela Schallmeiner	**Austrian QP Association** Deputy Chair.
Dr Ute Schleyer	**Vetter Pharma Fertigung** Project Manager, Site & Plant Development.
Stefan Schöttle	**Roche Diagnostics** Head of Informatics Pharma Manufacturing Mannheim.
Arno Terhechte	**Regional Council Münster** GMP Inspector.
Patrick Vanhecke	**GSK Vaccines** Expert in Isolator and Aseptic Filling Technologies and Room decontamination process.
Miro Zdilar	**Teva** Senior Manager Global IT Q&C - ERP & Value Chain.

ECA – Modern Sterile Operations

100% Control of Parenterals

9 April 2019

Objectives

You will get an overview on GMP- & compendial requirements for the testing of sterile pharmaceutical products concerning container-/Closure-Integrity testing and inspection of particles: what is state-of-the-art in the pharmaceutical industry is and which technologies are available.

Background

The 100% visual inspection of parenteral medicines, irrespective of the container type, is a requirement of the pharmacopeias. The inspection can be done manually or automatically – the latter being increasingly used. This is different for the testing of the integrity of the container/closure system. Here a 100% testing is only officially required for containers closed by fusion, e.g. ampoules. But, as the risk of unsterile containers due to cracks or leakages is high for the patient, some pharmaceutical companies also increasingly test the whole batch for integrity. This 100% testing is done with automated systems with different techniques, dependent on the type of container.

In this conference we will discuss:

- What are the authorities' actual/future requirements?
- Which primarily automated testing techniques are available?
- What will change due to the revision of EU Annex 1?
- What are the requirements for Data Integrity for the automated testing systems?

Moderator

Jörg Zimmermann, *Vetter Pharma Fertigung*

Target Audience

This conference is directed at specialists from the areas engineering, production and QA dealing with the implementation and operation of automated systems for the CCI testing or visual inspection of sterile medicinal products.

Programme

Thomas Reiner
Berndt+Partner

Pharmaceutical industry in digital change

Pharmacopeial- and GMP-requirements for visual Inspection
Dr Daniel Müller, *GMP Inspectorate Baden-Württemberg*

- Manual inspection (training, working place, qualification)
- Automated inspection (system validation and re-validation)
- Test sets (usage, storage, quality aspects)
- AQL testing as part of batch release
- Handling of rejects and ejects

Pharmacopeial- and GMP-requirements for Container-/Closure-Integrity Testing
Dr Daniel Müller, *GMP Inspectorate Baden-Württemberg*

- Test of ampules
- Test of vials and syringes, 100% vs sampling
- Test methods: blue dye test and others
- Inspection findings

Data Integrity & Audit Trail Review for Visual Inspection Systems
Felix Krumbein, *Roche Diagnostics*

- General regulatory requirements regarding data integrity
- Complete, consistent, and accurate data in the context of Visual Inspection Systems
- Data integrity starts with a proper user access management
- Batch-wise modification of product-related configuration parameters
- Audit Trail review concepts

Case Study Novartis: Fully automated Inspection Validation
Gabriel Anderson, *Novartis*

- New machine qualification
- Operational qualification
  - Particle defect detection
  - Physical defect detection
  - Leak detection equipment
- Performance qualification
  - Running conditions
  - Sampling plan

Case Study Rommelag CMO – 100% inline CCI Testing and particle inspection of BFS ampoules
Dr Martin Haerer, *Rommelag*
Dr Matthias Kahl, *Wilco*

- Project overview
- Technical & regulatory requirements
- Machine concept
- Sample preparation
- Qualification and Validation
- Operation of the inspection system

In the practical part of the conference, suppliers will show you different components and solutions. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts.

- **Head Space Analysis for difficult to inspect containers**
  Wilco
- **Container-/Closure Integrity Testing with Nitrogen**
  Lippok & Wolf
- **TBD**
  Heuft

Sterile Filtration

10 April 2019

Objectives

- You will be informed on new regulatory and technological developments in sterile filtration
- You learn the influence of the Annex 1 revision to sterile filtration and how to interpret the requirements to PUPSIT (Pre Use Post Sterilisation Integrity Test)
- You will get case studies from pharmaceutical companies
- Live Demos will show you how technologies perform

Background

Sterile Filtration is especially in the aseptic manufacture of medicinal products still the sterilisation method no 1 choice. The first draft of the Annex 1 revision defines comprehensive requirements wirh regard to the sterilisation. In light of these requirements the conference focuses on their practical implementation in pharmaceutical operations- and will also cover the controversially discussed question on pre-use post sterilisation integrity test.

Moderator

Jörg Zimmermann, *Vetter Pharma Fertigung*

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as from suppliers who have to deal with sterile filtration technologies in clean in their daily practice.

Programme

Klaus Eichmüller **EU GMP Inspection in Sterile/Aseptic Production**
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany

Sterile Filtration - GMP inspector's view
Dr Daniel Müller, *GMP Inspectorate Baden-Württemberg*

- Sterilisation methods & sterile filtration
- Reguatory documents on sterile filtration
- Draft Annex 1: requirements for sterile filtration process
- State of the art equipment & processing
- Experience from GMP inspections

In the practical part of the conference, suppliers will show you different components and solutions. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts.

- **Adoption of a Single-Use Sterile Filtration Assembly**
Merck Chemicals
- **Sterilizing-grade Filtration in Biopharmaceutical Applications**
Pall Life Science

Case study: Inline-Filtration using peristaltic pump: Implementation of a pressure control
Doris Rottenbusch, *Vetter Pharma-Fertigung*

- Initial request from FDA
- Technical concept phase: market research and laboratory studies
- Implementation of a prototype set-up on a filling line
- Practical experience
- Outlook

Sterile filtration – microbiological filter validation
Matthias Schaar, *Novartis Pharma*

- Requirements
- Initiating a scale down study
- How is the correlation to filter integrity testing

Bild: Pall

Bild: Merck

ECA – Aseptic Processing
Current Aseptic Technologies

9 April 2019

Objectives

Reasons to attend this conference:

- You will be informed on new regulatory and technological developments in sterile / aseptic manufacture
- You learn how current GMP and production requirements have to be implemented technologically in sterile manufacture
- You will get case studies from pharmaceutical companies
- Live Demos will show you how technologies perform

Background

GMP regulations only define general requirements for equipment – it has to be suitable for the intended work process, easy to clean and without any negative influence on the product quality. Questions like how these general requirements have to be fulfilled concretely in sterile manufacture, which points call for special attention and which new technologies will be used in the future are in this conference's focus. Speakers from the pharmaceutical industry and from planning and engineering companies deal with pivotal developments in the field of sterile manufacture.

Moderator

Gert Moelgaard, *ECA Validation Interest Group*

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice.
It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / Technology

Programme

Thomas Reiner
Berndt+Partner

Pharmaceutical industry in digital change

Innovative therapeutic options – a challenge to aseptic technologies
Gert Moelgaard, *ECA Validation Interest Group*

The landscape of pharmaceutical products and production is changing fast at the moment. The next generation of treatments becomes a reality and raise significant challenges to production, facilities and technologies of the future. New therapies are making significant progress and the pharmaceutical manufacturing is starting to adapt to the challenges.

The evolution of current aseptic technologies
Dr Friedrich Haefele, *Boehringer Ingelheim Pharma*

Today's aseptic production and regulations holds many interesting possibilities, mainly due to new process improvements such as biotech titer improvements, single use technology and flexible aseptic production technologies and 100% inline controls. The new regulations on EU Annex 1 on Sterile Products and Annex 17 on Real Time Release Testing and Parametric Release gives new challenges and opportunities for practical production.

Delivery of a Flexible Aseptic Filling Facility to a CMO
Dr Abdulaziz Awad, *Saudi Biotechnology Manufacturing Company*

- Platforms Modular Aseptic Solutions (MAS) for new facility design
- Flexibility in design options
- Off-site construction
- Flexibility of filling in pre-sterilized containers
- Flexibility formulating in different batch sizes
- Flexibility of adding lyophilization of mAb products

In the practical part of the conference, suppliers will show you different components and solutions. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts.

- **Bosch PreVAS Single-Use Dosing System**
  PreVAS means: - PreValidated / - PreAssembled / PreSterilized

Robert Bosch

- **Sterilizer validation / qualification made easy**

Ellab

- **Fully automatic and integrated particle detection system for filters in hot air sterilization tunnels and LAF units**

Bausch + Ströbel

- **Vial filling line VIRTUAL REALITY experience**

Steriline

Case study Vetter Pharma-Fertigung: Next steps in the development of V-CRT®; Analytical monitoring of H_2O_2 decontamination processes
Dr Ute Schleyer, *Vetter Pharma-Feritung*

- Within the Vetter Cleanroom Technology (V-CRT®) concept a batch specific H_2O_2 decontamination of the entire cleanroom mitigates the risk of microbial contamination
- To mitigate the risk of the decontamination agent on the drug product, an encompassing H_2O_2 monitoring system was established
- Whereas H_2O_2 is continuously monitored in the cleanroom, analysis of filled syringes, cartridges and vials is carried out upon customer's request
- Therefore, the advanced technology together with the comprehensive analytical approach reaches quality and safety standards well exceeding cGMP requirements

Substitution of formaldehyde room decontamination by hydrogen peroxide and acceleration of decontamination process by application of innovative catalyst technology for effective decomposition of hydrogen peroxide
Stefan Bieler, *IDT-Biologika*

- Required performance of the decontamination process (kill of bacterial and viral bio indicators)
- Comparison of the different decontamination processes regarding room and HVAC requirements
- Implementation of catalysts in different room and HCAV scenarios
- Acceleration of degassing process with catalyst (presenting tests results)
- Principle of heterogeneous H_2O_2 catalysis

Objectives

This is why you will benefit from attending this conference:

- Case studies from various pharmaceutical companies deal with the implementation, qualification and operation of Barrier Systems.
- You will discuss the current state of the art and new technological developments in Barrier Systems technology.
- You will get to know first hand the new EU-GMP Annex 1 draft requirements on Isolatores and RABS
- Experts from pharmaceutical companies will share their knowledge regarding operational experience.

Background

The protection against microbial contamination is the most important point for drugs produced by aseptic processes. Today the regulators require a more strict separation between operators and product in the form of an access barrier.

Two systems are on the market – RABS (Restricted Access Barrier System) and Isolators. But only isolators are referred to by the US FDA as advanced aseptic technology.

This conference will focus on current questions of barrier systems coming from FDA regulations as well as from the revised EU-GMP Annex 1, and it will specifically address the subject from the perspectives of pharmaceutical operators, planners and engineers.

Moderator

Didier Meyer, *DMCompliance*

Target Audience

This event is directed at decision-makers from pharmaceutical production, development and quality assurance/control. It also addresses engineers and planners who need to be well informed about current developments in the field of barrier systems.

Programme

Klaus Eichmüller
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany

EU GMP Inspection in Sterile/Aseptic Production

Closure Processing System for rubber stoppers: key aspects to consider to ensure process robustness in routine production
Sandrine Favre, *Octapharma*

- Introduction into Octapharma project
- CPS design phase
- Cycle development and process characterization
- Learnings

Case study GSK Vaccines: Isolator decontamination by H_2O_2 nebulization process
Patrick Vanhecke, *GSK Vaccines*

- VHP process versus H_2O_2 nebulization process
- Cycle development for nebulization process
- Pros and Cons for both processes
- Manufacturing applications

Key considerations for gene therapy manufacturing from early stage to fill-finish operations
Thomas Page, *Fujifilm Diosynth Biotechnologies*

- The importance of flexibility and high containment requirements;
- Applications of closed systems in designing the manufacturing process
- Differences in facility design, qualification and validation for gloveless isolators versus conventional isolators and
- Treating facilities as pieces of equipment for advanced therapy manufacturing

In the practical part of the conference, suppliers will show you different components and solutions. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts.

- **DECOpulse® – The H_2O_2 bio-decontamination system with atomization-driven evaporation**

Metall + Plastics

- **TBN**

MK Versuchsanlagen und Laborbedarf

The specific case of use of isolators and biosafety cabinets type III in Hospital Pharmacy
Prof Farshid Sadeghipour, *Lausanne University Hospital*

- Isolators for Non-Toxic Aseptic preparations
- Isolators and BSC an for Cytostatic Injectable preparations
- Sterility testing
- Perspectives with ATMP
- Perspectives with automation

Image: Skan

Image: Bosch

ECA – Data Integrity

9 April 2019

Objective

- You will get a deeper understanding what European inspectors expects from pharmaceutical companies in regard to Data Integrity
- You will learn how to prepare your company for an successful inspection in regard to Data Integrity
- You will learn how to investigate Data Integrity issues in your company especially in manufacturing and engineering
- You will discuss supplier's responsibility in Data Integrity compliance

Background

Even Data Integrity is one of the basic GMP principles since years multiple Data Integrity citations were reported by FDA und European inspectors during the last 3 years. Many US Warning Letters and EU Non-Compliance Reports deal with serious Data Integrity violations. Data Integrity questions have been and will continue be the focus of many GMP inspections.

As a consequence international authorities – FDA, EMA, PIC/S, WHO, MHRA - published (draft) documents to describe the regulatory expectations of Data Integrity.

Although all guidelines are not intended to impose additional regulatory burden to the regulated companies, a lot of uncertainty predominates the pharmaceutical industry how to implement these requirements into the daily business and how to integrate supplier's experience.

Programme

Thomas Reiner
Berndt+Partner

Pharmaceutical industry in digital change

Data Integrity in manufacturing and engineering environments - Another source of weaknesses or Compliance by Design?
Yves Samson, *ECA DI & IT Compliance Interest Group*

- Identifying applicable data integrity requirements
- Design review: how to promote and to secure compliant design
  - Product, process, data, system
- Securing data integrity during the engineering and commissioning activities
- Necessity to rely on secure and robust IT infrastructure

Requirements in Data Integrity
Dr Gerald Kindermann, *F. Hoffmann La-Roche*

- Data Integrity – Data species & ALCOA principles
- Hot topic - Myths Critical factors for DI program
- DI problems
- Case study DI in the manufacturing area System / data mgmt.
- User set up

Requirements for Operating Computerized Systems and Data Management
Dr Philip Hörsch, *Vetter Pharma-Fertigung*

- Data Integrity: Definitions and requirements for operating computerized systems
- Risk-based evaluation of data management (data input and output during operation) and follow-up activities for application (e.g. data review)
- Application of data management evaluation in case of new system acquisition and for assessment of existing systems
- Examples from quality control and manufacturing (aseptic, secondary packaging)

Data Integrity from a QP's Perspective
Gabriela Schallmeiner, *Austrian QP Association*

- The Regulatory Pillar
  - regulatory baseline on data integrity
  - regulatory Impact on the Qualified Person (QP)
- The Qualified Person's "Data" Challenge
  - Quality Management (QM) System Fundamentales
  - How GMP documents/data are related
- Make Data Integrity Integral to a Qualified Person's Daily Work
  - Data Integrity Impact on the QP
  - What gives a QP the confidence to certify a batch

How QA can check for data integrity in electronic systems
Knud Ryhl, *Novo Nordisk*

- A practical approach to data integrity
- Examples of where to look for applied data integrity
- How to approach data integrity when you have no clue of where to start
- Computer systems are manageable

Inspecting DI in Manufacturing – what does an inspector expect?
Dr Arno Terhechte, *Regional Council Münster*

- Regulatory Update (Chapter 4, Annex 11, PIC/S Guidance Good Practices for Data Management and Integrity)
- Definitions of Data, Raw Data, original data in Manufacturing
  - Aggregation of Data
  - Paper Records versus Continuous Monitoring / E-Records
- Upgrade / Modernizing the QMS with regard to Data Integrity
- Self Inspection, Assessment, Data Flow Analysis
- Data Integrity with regard to Outsourced Activities
- Data Integrity during Inspection / Inspection Findings

Moderator

Yves Samson, *Kereon & CEO, e-Compliance SME*

Target Audience

- Managers and staff from Manufacturing, QA and Engineering of pharmaceutical companies and suppliers
- Auditors (internal and external) responsible for performing self-inspections or external audits and needing to understand and assess data integrity

Programme

Klaus Eichmüller
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany

EU GMP Inspection in Sterile/Aseptic Production

Data Integrity requirements to technical suppliers – Expectations to equipment suppliers and engineering service providers
Yves Samson, *ECA DI & IT Compliance Interest Group*

- Regulatory management: knowing and understanding regulatory requirements
- Configurability to support customer process requirements
- System design expectations
- Cybersecurity requirements and constraints for equipment
- Effective support of review activities

Audit trail functionality and review – expectations from an inspector
Ib Alstrup, *Danish Medicines Agency*

- Good documentation practice
- Qualities of the audit trail functionality
- Qualification of the audit trail functionality
- Audit trail review

Expectations of an inspector on a training system with respect to data management
Klaus Eichmüller, *Wolnzach, c/o Regional Council Darmstadt*

- Introduction
- Expectations on the system
- Expectations not met - examples

A Paperless Lab, a Good Idea for Data Integrity, Risk Minimization and Lean Management?
Dr Thomas Meindl, *Labor LS*

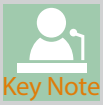
- Data integrity by avoidance of human errors by use of electronic data evaluation and documentation
- Minimization of contamination risk due to contaminated paper.
- Optimization and reduction of errors by implementation of electronic workflows
- Paper management: avoidance of excessive use of prints in order to save space in physical archives

Data Integrity Assessment Manufacturing: Preparation, Conducting and Remediation Activities
Stefan Schöttle, *Roche Diagnostics*

- Authorities focus
- Corporate Guidelines
- Assessment Project
- Best practises
- Challenges

TBD
Miro Zdilar, *Teva*

Programme

Time	ECA – Modern Sterile Operations 100% Controf of Parenterals	ECA – Aseptic Current Asepti
9:00 h		
9:15 h		Pharmaceutical Indu *Thomas Reiner, CE*
9:30 h		
9:45 h		
10:00 h		
10:15 h		Bre
10:30 h	Pharmacopeial- and GMP-requirements for visual inspection *Dr Daniel Müller, GMP Inspectorate Baden-Württemberg*	Innovative therapeutic options – a challenge to asepti *Gerd Moelgaard, ECA Validation Interest Group*
10:45 h		
11:00 h		
11:15 h	Pharmacopeial- and GMP-requirements for Container-/Closure-Integrity testing *Dr Daniel Müller, GMP Inspectorate Baden-Württemberg*	The evolution of current aseptic technologies *Dr Friedrich Haefele, Boehringer Ingelheim Pharma*
11:30 h		
11:45 h		
12:00 h		
12:15 h		
12:30 h		Lunch
12:45 h		
13:00 h		
13:15 h		
13:30 h	Data Integrity & Audit Trail Review for Visual Inspection Systems *Felix Krumbein, Roche Diagnostics*	Delivery of a Flexible Aseptic Filling Facility to a CMO *Dr Abdulaziz Awad, Saudi Biotechnology Manufacturing Compar*
13:45 h		
14:00 h		
14:15 h	Case Study Novartis: Fully automated inspection validation *Gabriel Anderson, Novartis*	Bosch PreVAS Single-Use Dosing System – PreVAS mea PreSterilized – *Bosch*
14:30 h		Sterilizer validation / qualification made easy *Ellab*
14:45 h		Fully automatic and integrated particle detection system *Bausch + Ströbel*
		Vial filling line VIRTUAL REALITY experience *Steriline*
15:00 h		
15:15 h		Bre
15:30 h		
15:45 h	Case Study Rommelag CMO – 100% inline CCI Testing and particle inspection of BFS ampoules *Dr Martin Haerer, Rommelag* *Dr Matthias Kahl, Wilco*	Case study Vetter Pharma-Fertigung: Next steps in the decontamination processes *Dr Ute Schleyer, Vetter Pharma-Fertigung*
16:00 h		
16:15 h		
16:30 h	Head Space Analysis for difficult to inspect containers *Wilco*	Substitution of formaldehyde room decontamination b nation process by application of innovative catalyst tec peroxide *Stefan Bieler, IDT-Biologika*
16:45 h	Container-/Closure Integrity Testing with Nitrogen *Lippok & Wolf*	
17:00 h	TBN *HEUFT*	
17:15 h	Discussion	Discussion
17:30 h		
18:00 h		Social Event for Congress Dele

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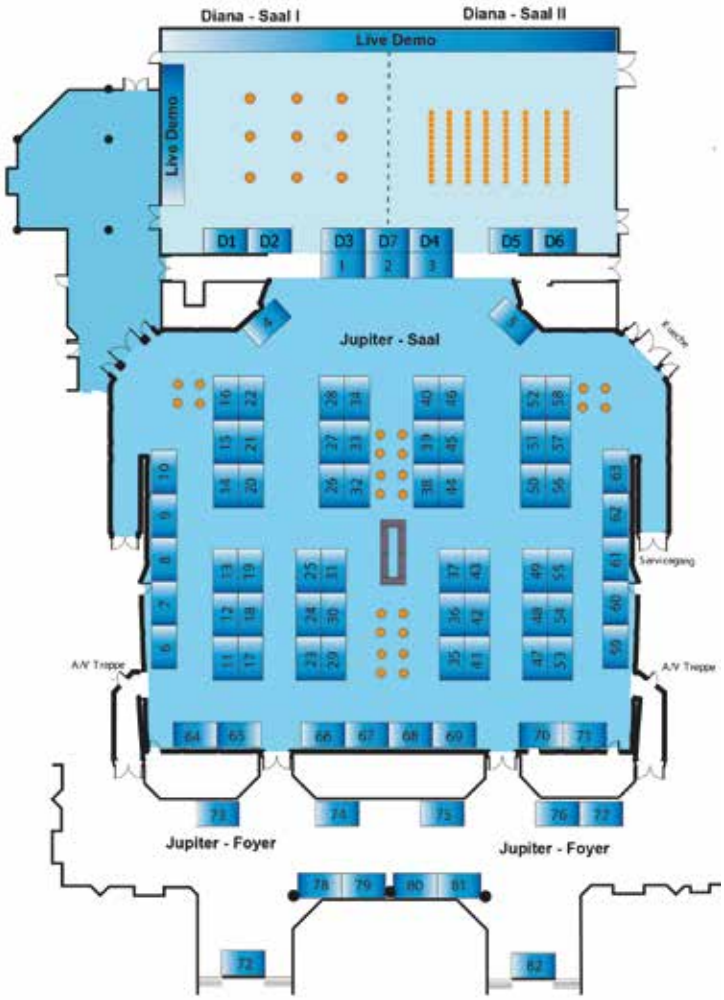
Technologies c Technologies	ECA – Data Integrity	Time
stry in digital change *EO, Berndt+Partner*		9:00 h 9:15 h 9:30 h 9:45 h
eak		10:00 h 10:15 h
c technologies	Data Integrity in manufacturing and engineering environments - Another source of weaknesses or Compliance by Design? *Yves Samson, ECA DI & IT Compliance Interest Group*	10:30 h 10:45 h 11:00 h
	Requirements in Data Integrity *Dr Gerald Kindermannm, F. Hoffmann La-Roche*	11:15 h 11:30 h 11:45 h
n Break		12:00 h 12:15 h 12:30 h 12:45 h 13:00 h 13:15 h
y	Requirements for Operating Computerized Systems and Data Management *Dr Philip Hörsch, Vetter Pharma Fertigung*	13:30 h 13:45 h 14:00 h
ns: - PreValidated / - PreAssembled / n for filters in hot air sterilization tunnels and LAF units	Data Integrity from a QP's Perspective *Gabriela Schallmeiner, Austrian QP Association*	14:15 h 14:30 h 14:45 h
eak		15:00 h 15:15 h 15:30 h
development of V-CRT®; Analytical monitoring of H_2O_2	How QA can check for data integrity in electronic systems *Knud Ryhl, Novo Nordisk*	15:45 h 16:00 h 16:15 h
by hydrogen peroxide and acceleration of decontami- chnology for effective decomposition of hydrogen	Inspecting DI in Manufacturing – what does an inspector expect? *Dr Arno Terhechte, Regional Council Münster*	16:30 h 16:45 h 17:00 h
	Discussion	17:15 h 17:30 h
egates, Speakers and Exhibitors		18:00 h

Programme

Time	ECA – Modern Sterile Operations Sterile Filtration	ECA – Asepti RABS & I
9.00 h 9:15 h 9:30 h		EU GMP Inspection in St *Klaus Eichmüller, Wolnzach, c/o Regiosnal Co*
9:45 h 10:00 h		Bre
10:15 h 10:30 h 10:45 h	Sterile Filtration - GMP inspector's view *Dr Daniel Müller, GMP Inspectorate Baden-Württemberg*	Closure Processing System for rubber stoppers: key asp routine production *Sandrine Favre, Octapharma*
11:00 h 11:15 h 11:30 h	Adoption of a Single-Use Sterile Filtration Assembly *Merck Chemicals* Sterilizing-grade Filtration in Biopharmaceutical Applications *Pall Life Sciences* 	Case study GSK Vaccines: Isolator decontamination by *Patrick Vanhecke, GSK Vaccines*
11:45 h 12:00 h 12:15 h 12:30 h 12:45 h		Lunch
13:00 h 13:15 h 13:30 h	Case study: Inline-Filtration using peristaltic pump: Implementation of a pressure control *Doris Rottenbusch, Vetter Pharma-Fertigung*	Key considerations for gene therapy manufacturing fro *Thomas Page, Fujifilm Diosynth Biotechnologies*
13:45 h 14:00 h 14:15 h	Sterile filtration – microbiological filter validation *Matthias Schaar, Novartis Pharma*	DECOpulse® – The H_2O_2 bio-decontamination system v *Metall + Plastics* TBN *MK Versuchsanlagen und Laborbedarf*
14:30 h 14:45 h		Bre
15:00 h 15:15 h 15:30 h	TBN	TBN
15:45 h 16:00 h 16:15 h	TBN	The specific case of use of isolators and biosafety cabin *Prof Farshid Sadeghipour, Lausanne University Hospital*
16:30 h 16:45 h 17:00 h	Discussion	Discussion

c Processing solators	ECA – Data Integrity	Time
erile/Aseptic Production *uncil Darmstadt, GMP Inspectorate, Germany*		9.00 h 9:15 h 9:30 h
eak		9:45 h 10:00 h
pects to consider to ensure process robustness in	Data Integrity requirements to technical suppliers - Expectations to equipment suppliers and engineering service providers *Yves Samson, ECA DI & IT Compliance Interest Group*	10:15 h 10:30 h 10:45 h
H_2O_2 nebulization process	Audit trail functionality and review – expectations from an inspector *Ib Alstrup, DMA*	11:00 h 11:15 h 11:30 h
Break		11:45 h 12:00 h 12:15 h 12:30 h 12:45 h
m early stage to fill-finish operations	Expectations of an inspector on a training system with respect to data management *Klaus Eichmüller, Wolnzach, c/o Regional Council Darmstadt*	13:00 h 13:15 h 13:30 h
vith atomization-driven evaporation Live Demos	A Paperless Lab, a Good Idea for Data Integrity, Risk Minimization and Lean Management? *Dr Thomas Meindl, Labor LS*	13:45 h 14:00 h 14:15 h
eak		14:30 h 14:45 h
	Data Integrity Assessment Manufacturing: Preparation, Conducting and Remediation Activities *Stefan Schöttle, Roche Diagnostics*	15:00 h 15:15 h 15:30 h
ets type III in Hospital Pharmacy	TBN *Miro Zdilar, Teva*	15:45 h 16:00 h 16:15 h
	Discussion	16:30 h 16:45 h 17:00 h

The exhibitors of the exhibition PharmaTechnica



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☐ **Day 1 (9 April 2019):** I would like to attend the Congress on day 1. I'm primarily interested in the conference:

- ☐ ECA Modern Sterile Operations – 100% Control of Parenterals
- ☐ ECA Aseptic Processing – Current Aseptic Technologies
- ☐ ECA Data Integrity

☐ I would also like to take part in the Social Event on the evening of 9 April 2019.

☐ **Day 2 (10 April 2019):** I would like to attend the Congress on day 2. I'm primarily interested in the conference:

- ☐ ECA Modern Sterile Operations – Sterile Filtration
- ☐ ECA Aseptic Processing – RABS & Isolators
- ☐ ECA Data Integrity

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