PHARMA CONGRESS
Production & Technology

15-17 September 2020

LIVE ONLINE

PROGRAMME

CURRENT ASEPTIC TECHNOLOGIES

CURRENT ASEPTIC COMPLIANCE

DATA INTEGRITY

BARRIER SYSTEMS

2020 PHARMA CONGRESS
LIVE ONLINE Production & Technology
network. experience. benefit. 15-17 September 2020

CONCEPT HEIDELBERG
Pharmaceutical Quality
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PHARMA CONGRESS
Production & Technology
15-17 September 2020 LIVE ONLINE

Benefit from your colleagues' experience and from the direct information exchange at the Pharma Congress 2020 again. The guiding theme from 15-17 September 2020 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.

The Pharma Congress Steering Committee


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


Dr Rainer Schmidt, F. Hoffmann-La Roche AG
Formerly Site Manager Kaiseraugst


Jörg Zimmermann, Vetter Pharma-Fertigung
Vice President Vetter Development Service, External Affairs


Dr Johannes Krämer, CSL Behring
Manager Engineering


Prof Franz Maier
Formerly Manager Technology, Nycomed


Roland Szymoniak, Sanofi
Manager Industrial Engineering & Transfer


Gert Moelgaard, ECA Validation Interest Group
Consultant, Moelgaard Consulting


Frank Studt, Gempex
Managing Director


Günter Körblein, Tetragon Consulting
Senior Consultant

Pharma Congress – Overview

Key Note 15 September


Annex 1 Revision – the long and winding road
Dr. Bernd Renger, *Immediate Past Chair, European Qualified Person Association*

- The drivers of change
- New paradigms and concepts
- Contamination Control and Quality Risk Management
- Stakeholder consultation
- New expectations to Media Fills and Lyophilisation
- The big challenges – CCIT and PUPSIT

Key Note 16 September



Case Study AbbVie: The new Biologics Site in Singapore
Dr. Rolf Ratke, *Abbvie* | **Ronan Mc Garvey**, *Abbvie*

- The Site strategy
- Products, processes & equipment
- Cooperation with EMA, blueprint to prepare for the successful pre-approval-inspection
- From start- up to realization until approval

Conferences — One Day Ticket € 690,-	15 September 9:00–17:00 h	16 September 9:00–17:00 h
Barrier Systems		✓
Data Integrity	✓	✓
Current Aseptic Technologies	✓	
Current Aseptic Compliance		✓
Virtual Exhibition PharmaTechnica	✓	✓

VIRTUAL EXHIBITION PHARMATECHNICA

Parallel to the conferences on 15 and 16 September and additionally on 17 September there will be the virtual exhibition PharmaTechnica. Take advantage of this opportunity to get to know new technologies, products and services at the virtual stands of the exhibitors.

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 follow any conference offered that day (you can also switch between the conferences any time).

CONTACT

For questions regarding content:
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ORGANISATION

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PLEASE NOTE!

Exhibition Visit: The virtual exhibition PharmaTechnica from 15-17 September 2020 will also be open to visitors who are not participating in the Congress. The visit of the exhibition does not entitle you to also participate in any of the conferences.

Congress Materials: All presentations will be provided prior to the Congress as Downloads.

With speakers from authorities and Industry (as of June 2020)

Sinéad Cowman	**Lonza** Global Business Development and Marketing Manager - Informatics.
Prof. Dr. Regine Eibl	**Zürcher University of Applied Science** Professor.
Hesham Elrayes	**B. Braun** Senior Auditor.
Dr. Rainer Gnibl	**Regierung von Oberbayern** GMP-Inspektor.
Fabio Gentilini	**BSP Pharmaceuticals** Project Manager.
Hannah Greiner	**Epista Life Science** Senior Consultant.
Dr. Martin Haerer	**Rommelag CMO** Head of Development / QP.
Dr. Philip Hörsch	**Vetter Pharma-Fertigung** Director QA - Validation/Risk Management/Trending.
Maria Kladi	**National Organization for Medicines, Greece** GMP Inspector.
Dr. Timo Krebsbach	**HHAC Labor Dr. Heusler** Managing Director.
Günther Kurta	**Boehringer Ingelheim** Head of technical documentation RCV.
Dr. Markus Lesch	**Vetter Pharma-Fertigung** Head of Microbiological Validation.
Prof. Dipl.-Ing. Franz Maier	**zuletzt Nycomed** Zuletzt Leiter der Hauptabteilung Technik.
Quentin Majeau	**Hydro-Fill** Director of the Single-Use Department.
Ronan McGarvey	**AbbVie** Director, Quality Operations.
Didier Meyer	**DMCompliance** Consultant at DMCompliance.
Gert Moelgaard	**ECA Validation Interest Group** Head of ECA Validation Interest Group; Moelgaard Consulting.
Dr. Daniel Müller	**Local GMP Authority of Baden Württemberg** Head of GMP Inspectorate.
Dr. Felix Oehme	**Bayer** Head of Biological Development Wuppertal.
Dermot O'Riordan	**EirGen** Sterile Technical Operations Manager.

With speakers from authorities and Industry (as of June 2020)

Dr. Rolf Ratke	AbbVie Director Biologics QA.
Dr. Bernd Renger	Immediate Past Chair of the European QP Association Bernd Renger Consulting.
Dr. Gabriele Sabine Roidl	Lonza Project Leader Drug Product Manufacturing.
Matthias Runge	Bayer Global Manufacturing Systems Technology Expert.
Yves Samson	ECA DI & IT Compliance Interest Group Kereon AG, CEO & e-Compliance SME.
Stefan Schöttle	Roche Diagnostics Nach 20 Jahren in der zentralen Informatik leitete Herr Schöttle bis zu seinem Vor-Ruhestand die Roche Pharma Informatik am Standort Mannheim.
Dr. Martin Schwab	Vetter Pharma-Fertigung Director Customer Project Management.
Leslie Southam	Oxford Biomedica QA Manager.
Rutger Vandiest	Bavarian Nordic Senior Director – Global head of sales, CDMO.
Dr. Ruud van Stigt	Curium EU Manufacturing, Supply Chain & MES Manager.
Dr. Sofia Venceslau	Genibet Biopharmaceuticals Project Manager.
Patrice Wery	GSK Vaccines Business Excellence Secondary - Head of Product Stewards.
Thomas Wibbeling	Miltenyi Biotec Manager Computerized Systems Validation.

ECA – DATA INTEGRITY | 15 SEPTEMBER 2020

Objective

- You will get a deeper understanding what European inspectors expect from pharmaceutical companies in regard to Data Integrity and how they deal with Data Integrity issues during inspections
- You will learn how to prepare your company for a 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 suppliers' responsibilities in Data Integrity compliance

Background

Even though Data Integrity has been one of the basic GMP principles for years, multiple Data Integrity citations have been reported by FDA und European inspectors during the last five years. Many US Warning Letters and EU Non-Compliance Reports deal with serious Data Integrity violations. Data Integrity questions have been and will continue to 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 suppliers' experience.

Moderator

Yves Samson, *ECA DI & IT Compliance Interest Group*

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 | ECA – DATA INTEGRITY | 15 SEPTEMBER 2020

Data Integrity from an Inspector's Point of View
Maria Kladi, *National Organization for Medicines, Greece*

- Data integrity and Good Documentation Practice
- Principles of Data Integrity
- WHO/FDA/MHRA Data Integrity Guidances
- Examples of Data Integrity issues

Data Integrity by Design
Stefan Schöttle, *Roche Diagnostics*

- Systems, Processes, Organizations
- Data Lifecycle based measures
- Best practice (dos and don'ts)
- Challenges today
- Available and emerging technologies

DI as topic of GMP-inspections; an inspector's view
Dr. Arno Terhechte, *Bezirksregierung Münster*

- Specific documents requested during preparation of an inspection
- How DI is addressed in the Quality Management resp. Data Governance system
- What is the company-specific definition of data (GxP-Data)?
- Specific activities during implementation / operation of compu-terized GxP systems (risk management, validation approach, backup, archiving, rolls and responsibilities)
- Data Flow in manufacturing and quality control
- Ensuring Compliance with regard to DI at service provider and contract manufacturers / labs
- Inspection findings

Case Study: A risk based approach for systematic DI-assessments and -mitigation
Hannah Greiner, *Epista Life Science*

- How to get started with DI gap assessments
- How to set up a systematic DI assessment approach
- How to document DI assessments
- How to identify high risk DI gaps that need immediate mitigation
- How to define a risk-based mitigation strategy
- Experiences with this risk based approach during a CS inspection by Austrian Authorities (AGES)

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

- Data Integrity: Definitions and requirements for operating compu-terized 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 Compliance Improvement: A Combined Approach to Mitigation
Matthias Runge, *Bayer*

- Challenges of a gap-based approach to ensure data integrity for a large number of computerized systems
- Ensuring data integrity with a general set of mitigation measures
- General mitigation measures combined with gap-based approach
- Practical experiences

ECA – DATA INTEGRITY | 16 SEPTEMBER 2020 – continued from 15 September 2020

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- You will get a deeper understanding what European inspectors expect from pharmaceutical companies in regard to Data Integrity and how they deal with Data Integrity issues during inspections
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Yves Samson, *ECA DI & IT Compliance Interest Group*

Target Audience

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PROGRAMME | ECA – DATA INTEGRITY | 16 SEPTEMBER 2020

Data Integrity implementation at Curium
Dr. Ruud van Stigt, *Curium*

- Intro Curium, the Nuclear Medicine company
- Direct Cause for follow up the program
- Why are we doing this
- Remediation plan
- What is next, where are we standing

Practical applications of Data Integrity and Audit Trail Review
Sinéad Cowman, *Lonza*

With the intro of the Data Integrity guidelines and the focus on the data management and security, the audit trail has become a primary focus of inspections. Understanding your Audit trail and the ability to review the data contained in it is now essential to compliance.

- Recommendations in understanding the audit trail functionality and approaches for validation.
- Importance of details of user requirements and user acceptance testing of audit trail functionality
- Review of the audit trail: System review vs Data review & Event logs vs. audit logs
- Identify and avoid typical pitfalls

Data Integrity in the interaction between business departments and IT as service provider
Thomas Wibbeling, *Miltenyi Biotec*

- Aspects of Data Integrity and their translation into "tangible" requirements
- Data Integrity and its implementation in SLAs between business units and IT
- IT strategy as a provider of shared services for the regulated environment

Data integrity from engineering to operations based on Comos DDMS at Boehringer Ingelheim
Günther Kurta, *Boehringer Ingelheim*

- How to validate a complex engineering tool landscape according to EU GMP Annex 11 and 15
- Change management (working layer technique)
- Assisted engineering document and data management (e.g. object-oriented engineering templates, IEC document classification, flexible unique tags)
- Approval workflows and electronic signature (CFR 21 Part 11)
- Electronic plant documentation (incl. fulltext search, redlining)
- Plant maintenance interface
- Future scenarios (brownfield enablement, scanning solution, intelligent P&ID)

Data Integrity and Process Validation: a virtuous circle
Yves Samson, *ECA Data Integrity & IT Compliance Interest Group*

- How much data are needed?
- Understanding the process
- Reporting validation
- Securing data integrity

ECA – CURRENT ASEPTIC TECHNOLOGIES | 15 SEPTEMBER 2020

Objectives

Reasons to attend this conference:

- You will be informed on new technological developments in sterile / aseptic manufacturing
- You will learn how current GMP and production requirements have to be implemented technologically in sterile manufacturing
- You will get case studies from pharmaceutical companies

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 manufacturing.

Moderator

Gert Moelgaard, *ECA Validation Interest Group*
Jörg Zimmermann, *Vetter Pharma-Fertigung*

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

Technological overview: Single-use technologies for intensified and continuous bioprocesses (USP & DSP)
Prof. Dr. Regine Eibl, *Zürcher University of Applied Science*

- Continuous USP
  - High cell density and large volume cell banks
  - N-1 perfusion
  - Production in perfusion mode
  - Clarification
- Continuous DSP
  - Bind-elute chromatography
  - Virus inactivation
  - Flow-through chromatography
  - Virus filtration
  - Final ultra- and diafiltration

Continuous Biomanufacturing - a GMP inspector's view
Dr. Daniel Müller, *Local GMP Authority of Baden-Württemberg*

- Regulatory guidance
- General requirements
- Application of single-use systems
- Control & validation strategy
- Challenges and discussion points

Case Study Bayer: Continuous Downstream Processing for manufacturing of protein therapeutics
Dr. Felix Oehme, *Bayer*

- Challenges and benefits of continuous manufacturing for biologics
- Case study: Comparison of process parameters and product quality in batch and continuous manufacturing
- Control strategy and regulatory aspects

Challenges in manufacturing high value lyophilized oncologics - a case study
Fabio Gentilini, *BSP Pharmaceuticals*

- BSP's requirements for a flexible CMO sterile suite with space constrains for high value oncological products containing solvents under isolation technology
- Suppliers provided solutions including:
  - Reduced foot-print equipment
  - Innovative loading/unloading system (including cold shelf loading)
  - PAT tools (including nucleation)

Case Study: Cycle Development & Validation of automated AHP decontamination processes for cleanrooms
Dr Markus Lesch, *Vetter Pharma-Feritung*

- Design of decontamination system & cleanroom
- Optimization of aerosolized amount of H_2O_2
- Selection of positions to be challenged with indicators
- Optimization of relative humidity
- Optimization of decontamination time
- Value of chemical indicators for validation of AHP processes

EirGen Pharma – How state-of-the-art fill & finish equipment flexibility supports CMO business
Dermot O'Riordan, *EirGen*

- Possibilities and challenges when processing various RTU packaging components
- Challenges of filling non- to high-potent products
- Flexibility in aseptic filling processes
- Challenges of manufacturing different products with different batch sizes

ECA – CURRENT ASEPTIC COMPLIANCE | 16 SEPTEMBER 2020

Objectives

Reasons to attend this conference:

- You will be informed on the current status of EU Annex 1 revision
- You will learn how current GMP and production requirements have to be implemented in sterile manufacture
- You will get case studies from pharmaceutical companies

Background

EU GMP Annex 1 on sterile medicinal products is currently under revision. A first public draft from 2017 was intensively discussed. A second public draft was published in February 2020 to comment again until July 2020. What are the consequences of these discussions and what are the next steps to a final document will be explained in this conference.

Moderator

Gert Moelgaard, *ECA Validation Interest Group*
Jörg Zimmermann, *Vetter Pharma-Fertigung*

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 regulations in their daily practice. It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / Technology

Case Study: Media Fill Design for aseptic Blow Fill Seal Filling
Dr. Martin Haerer, *Rommelag CMO*

- General Media fill concept
- Bracketing concept
- Intervention procedure
- Operator involvement
- Evaluation

Environmental Monitoring in Modern Biopharmaceutical DP Facilities – A Proposal for a Harmonized Risk Based Approach for Selecting Monitoring Points and Defining Monitoring Plans
Patrice Wery, *GSK Vaccines*

- What about Biophorum, the group working on this Risk Assessment?
- Why do we need a harmonized Risk Assessment tool?
- Explanation of the tool in a step by step approach
- First feed-back of authorities
- A practical example to illustrate how it works

Status of Annex 1 revision?
Dr. Rainer Gnibl, *Government of Upper Bavaria*

Single Use Bioreactor Platform(SUB) for Microbial Fermentation in a GMP manufacturing facility
Dr. Sofia Venceslau, *Genibet*

- Benefits for GMP production
- Broaden the use of SUBs to expand bacteria and yeast cells
- Main faced challenges

Challenges and Opportunities of Aseptic Manufacturing Process Transfers
Dr. Martin Schwab, *Vetter Pharma-Fertigung*

- Manufacturing Process Transfers / Clean Room Transfers: Background, Drivers, Characteristics
- Technology Transfer: Like for like, process optimization, gap- and risk-analysis, challenges
- Lessons learned and outlook

Areas of focus for Auditors of Sterile Operations
Hesham Elrayes, *B.Braun*

- Areas to be focused
  - APRs (PQRs)...
  - BRs
  - Deviations/Investigations
  - Training
  - Complaints
  - Adverse Events – Signal Detection
- What should I spend some time looking at here...?
  - Batches Manufactured
  - Analytical Data & Trend Analysis
  - Qualification status of equipment
  - Quality Agreements
  - Sterilization cycles
  - Environmental Monitoring
- Assessment tools to focus on key process and environmental elements relative to audit aseptic Lyophilization process

ECA – BARRIER SYSTEMS | 16 SEPTEMBER 2020

Objectives

This is why you will benefit from attending this conference:

- Case studies from various pharmaceutical companies will deal with the implementation, qualification and operation of Isolator and RABS 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 Barrier Systems
- 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 | ECA – BARRIER SYSTEMS | 16 SEPTEMBER 2020

From design to construction of a new integrated fill & finish facility – combination of proven and new technologies
Dr. Gabriele Sabine Roidl, *Lonza*

- Installation of a new drug production line
- Using modern and innovative technologies
- Vial filling line with isolator technology and 2 lyophilizers

Aseptic processing and filling of a viral vector for gene and cell therapy
Leslie Southam, *Oxford Biomedica*

- An integrated solution of a state of the art small batch filler in a barrier system, designed to fit a biological production process: Freeze/thaw and time restrictions of the product lead to a special line layout where formulation and filling are combined in one barrier system
- Application of No-touch-transfer (NTT): An alternative methodology to introduce pre-sterilized product containers into the Grade A environment without in process disinfection steps
- Aseptic Containment Approach: Requirements on containment driven by cross contamination control are combined with requirements for aseptic filling and viral containment

Barrier Systems and Annex 1: GMP inspectors's point of view
Dr. Daniel Müller, *Local GMP Authority of Baden-Württemberg*

- Most important changes of Annex 1 – an update
- Regulatory comparison of Annex 1 version 2018 and new / intended Annex 1
- GMP inspector's comments on new / intended requirements for barriers

New-Designed Isolator for Aseptic Filling
Quentin Majeau, *Hydro-Fill*

- Isolators : Overview
- Disposable Isolator to a Virtual-wall Isolator
- Virtual wall Isolator : containment or Class A operation
- Virtual wall Isolator : Integration on a disposable filling line


Vaccines for the World - Insights into Design and Execution of a BSL2 Fill-Finish Facility
Rutger Vandiest, *Bavarian Nordic*
Mark Miller, IPS

- The fill & finish operations for viral vaccines: specific attributes to facility and equipment
- Design, construction and qualification of their new fill & finish facility in Denmark
- Filling and lyophilization of live vaccines in a BSL2 environment
- Dedicated capacity for CDMO services

Writing User Requirement Specifications (URS) for Isolator projects
Dr. Timo Krebsbach, *HHAC Labor Dr. Heusler*

- The URS should define clearly and precisely, what the user wants the equipment to do in terms of performance characteristics, product quality metrics, and production yields. It should also define any nonfunctional requirements, constraints, and deliverables that need to be supplied with the system.
- The presentation shows the lesson learned from the view of a customer.
- In the future topics like automation and digitalization need more attention from the very beginning

AGENDA | 15 SEPTEMBER 2020

Time	ECA – Data Integrity	ECA – Current Aseptic Technologies	Time
9:00 h 9:15 h 9:30 h 9:45 h	**KEYNOTE:** Annex 1 Revision – the long and winding road *Dr. Bernd Renger, Immediate Past Chair, European Qualified Person Association*		9:00 h 9:15 h 9:30 h 9:45 h
10:00 h	Break		10:00 h
10:15 h 10:30 h 10:45 h	Data Integrity from an Inspector's Point of View *Maria Kladi, National Organization for Medicines, Greece*	Technological overview: Single-use technologies for intensified and continuous bioprocesses (USP & DSP) *Prof Dr Regine Eibl , Zürcher University of Applied Science*	10:15 h 10:30 h 10:45 h
11:00 h 11:15 h 11:30 h	Data Integrity by Design *Stefan Schöttle, Roche Diagnostics*	Continuous Biomanufacturing - a GMP inspector's view *Dr. Daniel Müller, Local GMP Authority of Baden-Württemberg*	11:00 h 11:15 h 11:30 h
11:45 h 12:00 h 12:15 h 12:30 h 12:45 h	Break		11:45 h 12:00 h 12:15 h 12:30 h 12:45 h
13:00 h 13:15 h 13:30 h	DI as topic of GMP-inspections; an inspector's view *Dr. Arno Terhechte, Bezirksregierung Münster*	Case Study Bayer: Continuous Downstream Processing for manufacturing of protein therapeutics *Dr. Felix Oehme, Bayer*	13:00 h 13:15 h 13:30 h
13:45 h 14:00 h 14:15 h	Case Study - A risk based approach for systematic DI-assessments and -mitigation *Hannah Greiner, Epista Life Science*	Challenges in manufacturing high value lyophilized oncologics - a case study *Fabio Gentilini, BSP Pharmaceuticals*	13:45 h 14:00 h 14:15 h
14:30 h 14:45 h	Break		14:30 h 14:45 h
15:00 h 15:15 h 15:30 h	Requirements for Operating Computerized Systems and Data Management *Dr. Philip Hörsch, Vetter Pharma Fertigung*	Case Study: Cycle Development & Validation of automated AHP decontamination processes for cleanrooms *Dr. Markus Lesch, Vetter Pharma-Fertigung*	15.00 h 15:15 h 15:30 h
15:45 h 16:00 h 16:15 h	Data Integrity Compliance Improvement: A Combined Approach to Mitigation *Matthias Runge, Bayer*	EirGen Pharma– How state-of-the-art fill & finish equipment flexibility supports CMO business *Dermot O'Riordan, EirGen*	15:45 h 16:00 h 16:15 h
16:30 h 17:00 h	Discussion	Discussion	16:30 h 17:00 h

AGENDA | 16 SEPTEMBER 2020

Time	ECA – Barrier Systems	ECA – Data Integrity	ECA – Current Aseptic Compliance	Time
9.00 h 9:15 h 9:30 h 9:45 h	**KEYNOTE:** Case Study AbbVie: The new Biologics Site in Singapore *Dr. Rolf Ratke, Abbvie | Ronan Mc Garvey, AbbVie*			9.00 h 9:15 h 9:30 h 9:45 h
10:00 h	Break			10:00 h
10:15 h 10:30 h 10:45 h	From design to construction of a new integrated fill&finish facility – combination of proven and new technologies *Dr. Gabriele Sabine Roidl, Lonza*	Data Integrity implementation at Curium *Dr. Ruud van Stigt, Curium*	Case Study: Media Fill Design for aseptic Blow Fill Seal Filling *Dr. Martin Haerer, Rommelag CMO*	10:15 h 10:30 h 10:45 h
11:00 h 11:15 h 11:30 h	Aseptic processing and filling of a viral vector for gene and cell therapy *Leslie Southam, Oxford Biomedica*	Practical applications of Data Integrity and Audit Trail Review *Sinéad Cowman, Lonza*	Environmental Monitoring in Modern Biopharmaceutical DP Facilities – A Proposal for a Harmonized Risk Based Approach for Selecting Monitoring Points and Defining Monitoring Plans *Patrice Wery, GSK Vaccines*	11:00 h 11:15 h 11:30 h
11:45 h 12:00 h 12:15 h 12:30 h 12:45 h	Break			11:45 h 12:00 h 12:15 h 12:30 h 12:45 h
13:00 h 13:15 h 13:30 h	Barrier Systems and Annex 1: GMP inspectors's point of view *Dr. Daniel Müller, Local GMP Authority of Baden Württemberg*	Data Integrity in the interaction between business departments and IT as service provider *Thomas Wibbeling, Miltenyi Biotec*	Status of Annex 1 revision? *Dr. Rainer Gnibl, Government of Upper Bavaria*	13:00 h 13:15 h 13:30 h
13:45 h 14:00 h 14:15 h	New-Designed Isolator for Aseptic Filling *Quentin Majeau, Hydro Fill*	Data integrity from engineering to operations based on Comos DDMS at Boehringer Ingelheim *Günther Kurta, Boehringer Ingelheim*	Single Use Bioreactor Platform(SUB) for Microbial Fermentation in a GMP manufacturing facility *Dr. Sofia Venceslau, Genibet*	13:45 h 14:00 h 14:15 h
14:30 h 14:45 h	Break			14:30 h 14:45 h
15:00 h 15:15 h 15:30 h	Vaccines for the World - Insights into Design and Execution of a BSL2 Fill-Finish Facility *Rutger Vandiest, Bavarian Nordic*	Data Integrity and Process Validation: a virtuous circle *Yves Samson, ECA Data Integrity & IT Compliance Interest Group*	Challenges and Opportunities of Aseptic Manufacturing Process Transfers *Dr. Martin Schwab, Vetter Pharma-Fertigung*	15:00 h 15:15 h 15:30 h
15:45 h 16:00 h 16:15 h	Writing User Requirement Specifications (URS) for Isolator projects *Dr. Timo Krebsbach, HHAC Labor Dr. Heusler*		Areas of focus for Auditors of Sterile Operations *Hesham Elrayes, B. Braun*	15:45 h 16:00 h 16:15 h
16:30 h 17:00 h	Discussion	Discussion	Discussion	16:30 h 17:00 h

EASY REGISTRATION

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Internet:
www.pharma-kongress.de
www.pharma-kongress.com

REGISTRATION FOR THE LIVE ONLINE PHARMA CONGRESS 2020

Participating in the Conferences of the Congress – One Day Ticket € 690,- (plus VAT)

(includes participation in any conference on that day and the visit of the virtual exhibition PharmaTechnica.)

With a one day ticket you can participate in any conference offered that day.

☐ **Day 1 (15 September 2020)**: I would like to participate the Congress on day 1. I'm primarily interested in the conference:
- ☐ ECA Data Integrity
- ☐ ECA Current Aseptic Technologies

☐ **Day 2 (16 September 2020):** I would like to participate the Congress on day 2. I'm primarily interested in the conference:
- ☐ ECA Barrier Systems
- ☐ ECA Data Integrity
- ☐ ECA Current Aseptic Compliance

PLEASE NOTE:
You will receive all presentations prior to the Congress as Download.

RESERVATION FORM

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

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CONCEPT HEIDELBERG
P.O. BOX 101764
Fax +49 (0) 62 21/84 44 34
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 2 weeks prior to the conference 10 %,
☐ until 1 weeks prior to the conference 50 %
☐ within 1 week 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 HEIDELBERGwill 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)!
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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