PHARMA CONGRESS
Production & Technology
Düsseldorf/Neuss, 15/16 September 2020

2020 PHARMA CONGRESS
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Production & Technology
DÜSSELDORF, 15-16 SEPTEMBER 2020

Data Integrity
Current Aseptic Technologies
Current Aseptic Compliance
Continuous Bioprocessing
Barrier Systems
Integrated Qualification with Suppliers

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Overview

Benefit from your colleagues' experience and from the direct information exchange at the Pharma Congress 2020 again – the guiding theme on 24/16 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. So, choose from presentations in five conferences.

Key Notes

Pharma-Kongress – 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 9:00–17:45 h	16 September 9:00–17:00 h
Data Integrity	✓	✓
Current Aseptic Technologies	✓	
Current Aseptic Compliance		✓
Continuous Bioprocessing	✓	
Barrier Systems		✓
Integrated Qualification with Suppliers	✓	
Exhibition PharmaTechnica	✓	✓

Steering Committee

Dr Friedrich Haefele
Boehringer Ingelheim
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gempex
Managing Director

Günter Körblein
Tetragon Consulting
Senior Consultant

Exhibition

2020 PHARMA CONGRESS PharmaTechnica DÜSSELDORF, 15-16 SEPTEMBER 2020

Parallel to the conferences on 15 and 16 September there will be the large exhibition PharmaTechnica. Take advantage of this opportunity to get to know new tech-nologies, 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 Congress Centrum Düsseldorf / Neuss
Rheinallee 1
41460 Neuss
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
emailus@cphotelduesseldorfneuss.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 15 September 2020, 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.

Contact

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ECA Continuous Bioprocessing:
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ECA Integrated Qualification with Suppliers:
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ECA Academy Your GMP/GDP Information Source

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 March 2020. 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 and via the Pharma Congress App. This app can be downloaded either by scanning the QR Code or by searching for PharmaEvents in the Apple / Google Play Store by end of January 2020.

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 March 2020)

Eva-Maria Baumgartner	**Syntacoll, Regensburg, Germany** Validation Manager
Sinéad Cowman	**Lonza** Global Business Development and Marketing Manager - Informatics.
Dirk Denecke	**Bayer** Quality Assurance Specialist.
Prof Dr Regine Eibl	**Zürcher University of Applied Science** Professor.
Hesham Elrayes	**B. Braun** Senior Auditor.
Holger Frey	**Merck KGaA, Darmstadt, Germany** Manager of the qualification group within Pharmaceutical Technology
Ralf Gengenbach	**gempex, Mannheim, Germany** Managing Director
Fabio Gentilini	**BSP Pharmaceuticals** Project Manager.
Hannah Greiner	**Epista Life Science** Senior Consultant.
Dr Friedrich Haefele	**Formerly Boehringer Ingelheim Pharma** Formerly Head of the department Biopharma Fill & Finish Germany.
Dr Martin Haerer	**Rommelag CMO** Head of Development / QP.
Dr Philip Hörsch	**Vetter Pharma-Fertigung** Director QA - Validation/Risk Management/Trending.
Peter Larsson	**Novo Nordisk, Bagsvaerd, Denmark** Head of Engineering Management in Novo Nordisk.
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.
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.

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

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.
Maarten Pennings	BiosanaPharma Chief Technical Officer.
Dr Ralf Ratke	AbbVie Director Biologics QA.
Dr Bernd Renger	Immediate Past Chair of the European QP Association Bernd Renger Consulting.
Dr Beate Reutter	Landesamt für soziale Dienste Schleswig-Holstein, Kiel, Germany GMDP-Inspector and head of the inspectorate.
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 Formerly Head of Informatics Pharma Manufacturing Mannheim.
Dr Martin Schwab	Vetter Pharma-Fertigung Director Customer Project Management.
Leslie Southam	Oxford Biomedica QA Manager.
Dr Arno Terhechte	Bezirksregierung Münster GMP-Inspektor/GMP Inspector.
Francois Vandeweyer	Form. Janssen Pharmaceutica
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.
Udara Yapa	MSD Animal Health Danube Biotech Site Validation Lead.
Jörg Zimmermann	Vetter Pharma-Fertigung Vice President Vetter Development Service, External Affairs.

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.

Programme

Dr. Bernd Renger
Immediate Past Chair,
European QP Association

Annex 1 Revision – the long and winding road

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 computerized 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 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 Compliance Improvement: A Combined Approach to Mitigation
Matthias Runge | Dirk Denecke, *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

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


Dr. Rolf Ratke, *AbbVie*
Ronan McGarvey, *Abbvie*

Case Study AbbVie: The new Biologics Site in Singapore

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

Practical Examples found and case studies on how to challenge DI potential issues
Swa Vandeweyer, *Formerly Janssen Pharmaceutica*

- Introduction and real life examples
- Practical challenges on potential DI issues in Production, Calibration, Quality Organisation

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
- 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 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

Programme

Dr. Bernd Renger
Immediate Past Chair,
European QP Association

Annex 1 Revision – the long and winding road

The evolution of Aseptic Technologies
Dr Friedrich Haefele, *formerly Boehringer Ingelheim Pharma*

- Technological trends in the development of biotechnology APIs
- Galenic challenges
- Technical trends in API production and production of finished dosage forms
- Regulations – do they make it harder or easier?

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)

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

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.

- **B+S Multi Dosing System - 3 in 1**
  Bausch + Ströbel
- **Collaborative robots**
  Steriline
- **Isolator Technology & RTP Transfer System**
  Metall + Plastic | Castus

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

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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. What are the consequences of this discussion 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

Programme


Dr. Rolf Ratke, *AbbVie*
Ronan McGarvey, *Abbvie*

Case Study AbbVie: The new Biologics Site in Singapore

Status of Annex 1 revision?
Dr Beate Reutter, *Landeesamt für soziale Dienste Schleswig-Holstein, Kiel, Germany*

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

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

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 – Continuous Bioprocessing

15 September 2020

Objectives

This conference provides an overview of the concepts of continuous processing and its level of adoption in the biopharmaceutical industry. Besides technological challenges, GMP questions related to continuous processing will be discussed.

Background

Continuous processing could be the next step for process intensification in the evolution of biopharmaceuticals. The biopharmaceutical industry is facing several challenges due to an increasing number of biosimilars and multiple therapies targeting the same indication which increases the costs but also reduces the required batch sizes. In addition, the expression levels for monoclonal antibodies could be increased by one order of magnitude which shifts the bottleneck further downstream, requiring an intensified operation in downstream processing.

Today's standard batch manufacturing is comprised of a cascade of processes where the product is routed through one unit operation at a time and is collected in hold containers in between. This can limit both facility utilization and productivity.

Integrated processing on the other hand includes the use of continuous unit operations where product moves through a series of unit operations without interruption. This design allows reducing the size of unit operations which translates into buffer, resin and consumable savings. Further advantages of continuous manufacturing are seen in unprecedented control over product quality, better agility and flexibility as well as reduced risks of scale-up through smaller equipment and facilities.

Several pharmaceutical companies have shown successful examples for both fully integrated and hybrid processing platforms and first steps towards regulatory approval have been taken. However, the decision for continuous processing has to be made on a case-to-case basis. It is recommended to perform risk assessments for the platform, the connections and the automation to meet the GMP requirements.

Moderator

Prof. Dr. Regine Eibl, *Zürcher University of Applied Science*

Target Audience

This conference is directed at executives from development, engineering, production and QA responsible for the implementation of continuous biomanufacturing.

Programme

Dr. Bernd Renger
Immediate Past Chair,
European QP Association

Annex 1 Revision – the long and winding road

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

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.

- **N.N.**

N.N.

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 Biosana: Continuous Manufacturing of biosimilar antibodies: a small company's journey to phase 1 clinical studies
Maarten Pennings, *BiosanaPharma*

In 2018 the first clinical study was performed with a Mab that was manufactured with a continuous process from bioreactor to bulk drug substance. In this talk an overview of the purification process, a number of design aspects, automation control and virus safety will be presented.

- Conversion to a fully continuous manufacturing process and run for weeks under GMP to produce Clinical Trial Material
- Design choices in the frequency of exchanging single use components impact manufacturability
- Challenges in downscaling to an appropriate model for viral clearance validation were addressed

Development of an integrated continuous downstream process for a monoclonal antibody production
N.N., *N.N.*

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

ECA – Barrier Systems

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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


Dr. Rolf Ratke, *AbbVie*
Ronan McGarvey, *Abbvie*

Case Study AbbVie: The new Biologics Site in Singapore

Grey Field Project for Production of Large Scale Bacterial antigen in an Aseptic Environment
Udara Yapa, *MSD Animal Health Danube Biotech*

- Planning, execution, commissioning and qualification and the technologies behind the vision
- Details of the Bacterial Antigen Production Line
- Challenges/complications and the complexity of the project
- Aseptic technology related to isolators will be discussed along with the single use connectors used in the process to maintain the containment of the project

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*

- 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

ECA – Integrated Qualification with Suppliers

15 September 2020

Objectives

A new ECA guideline on Integrated Qualification and Validation enables pharmaceutical companies and suppliers of pharmaceutical equipment and systems to cooperate more cost-effective than the traditional pharmaceutical approach to qualification. The guide is developed by a pharmaceutical companies and suppliers based on practical experience and document examples from many international commissioning and qualification projects.

The conference will give pharmaceutical professionals and suppliers of equipment, systems and engineering to the pharmaceutical industry will get an overview of the "Integrated Qualification & Validation" approach and the templates and examples for use in projects in the future. The conference includes experiences from both pharmaceutical customer, suppliers and engineering & consulting companies

- Cost-effective project cooperation models and templates
- Critical Aspects of manufacturing systems
- Good Engineering Practice and its influence to leverage qualification activities
- Cost-effective cooperation between suppliers and their pharmaceutical customers

Background

For pharmaceutical companies and suppliers to the pharmaceutical industry a good partnership on Testing, Qualification and Validation is increasingly important.

Project time and cost can be saved if the pharmaceutical requirements on Good Engineering Practices, Qualification and Validation are well known. Therefore ECA has developed a Good Practice Guide for "Integrated Qualification & Validation" - a guide to effective qualification based on Customer-Supplier partnership.

The guide has been developed in partnership between pharmaceutical companies and suppliers of equipment, systems and engineering to the pharmaceutical industry. The first draft was made public at a conference in Berlin in September 2018 with participation from both European regulators and US FDA.

Qualification and validation have been mandatory activities for many years in the pharmaceutical industry. But new international regulations based on quality risk management principles can enable a better and more cost-effective approach to design, testing and documentation of supplier activities - in partnership with pharmaceutical customers.

Additional Benefit

You will get a free copy of the ECA Good Practice Guide: "Integrated Qualification and Validation – A guide to cost effective qualification based on Customer--Supplier Partnership".

Moderator

Gert Moelgaard, *ECA Validation Interest Group*

Target Audience

Managers from the pharmaceutical industry and especially their suppliers of pharmaceutical equipment and services who

- may be influenced by the Annex 15 revision and FDA Process Validation Guidance regarding Qualification/Verification and Process Validation activities and
- want to see how an integrated approach to qualification and validation can enable successful fast-track projects.

Programme

Dr. Bernd Renger
Immediate Past Chair,
European QP Association

Annex 1 Revision – the long and winding road

Future qualification and validation involves suppliers
Gert Moelgaard, *ECA Validation Interest Group*

Pharmaceutical facility projects can save significant time and cost with good cooperation between customers and suppliers. Examples from USA, Europe and China demonstrates that there is a lot to win, compared with what most companies does today. ECA's new Good Practice Guide on Integrated Qualification and Validation is a useful tool that you should consider.

GEP for Suppliers – A Prerequisite for Fast Track Qualification projects?
Ralf Gengenbach, *gempex*

Good Engineering Practice (GEP) is an important part of successful qualification projects today and even more in the future. Suppliers of pharmaceutical equipment and systems need to understand the GEP principles, guidelines and requirements to ensure cost-effective and GMP compliant qualification projects.

Customer-Supplier Cooperation: A project example from Merck Healthcare KGaA
Holger Frey, *Merck*

Merck has good experience of cooperation with suppliers on the commissioning and qualification in recent projects. The success formula builds on building a close cooperation with the suppliers in a pharmaceutical project and the learnings from this can be an inspiration for other companies.

An effort to build smarter: Transforming Novo Nordisk´s qualification and validation concept to focus on GEP and supplier collaboration
Peter Larsson, *Novo Nordisk*

Novo Nordisk has recently implemented a new global approach to qualification and validation based on quality risk management principles including focus on GEP and supplier collaboration.
The presentation will outline the change and share experience from the transformation, especially regarding the cooperation with suppliers on qualification activities.

Using ECA's Modern Qualification Guide as a pharmaceutical customer
Eva-Maria Baumgartner, *Syntacoll*

Syntacoll has developed a cost-effective approach to qualification and validation together with their suppliers. They are using a cost-effective approach based on categories of equipment which is a benefit during qualification. The presentation will share the customer perspective on expectation from their suppliers and an integrated approach to qualification and validation.

Panel Discussion
Gert Moelgaard, *ECA Validation Interest Group*
Ralf Gengenbach, *gempex*
Holger Frey, *Merck*
Peter Larsson, *Novo Nordisk*
Eva-Maria Baumgartner, *Syntacoll*

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Lottery

As every year there is also a lottery this year – and again with various interesting prices. So you may want to participate – it's worth it! All you have to do is to have 10 exhibitors confirm your visit at their stand by signature and stamp on the lottery pass. Then drop the completed pass at the congress registration desk and you'll participate. Lottery passes are available at the registration. Please note: The winner will be drawn and notified after the Congress.

Live Demos

The Live Demos integrated in some conferences in 2014 for the first time have made the Pharma Congress even more practical. The aim of these demos is not only to present technology at the conferences, but also to make it a real experience. That's why this year you'll find Live Demos as part of individual conferences as well as other "free" Demos during the breaks. In the agenda on the following pages you will find an overview of all presentations in which the leading companies will demonstrate their latest products and services.

Live Demos

Programme – 15 September 2020

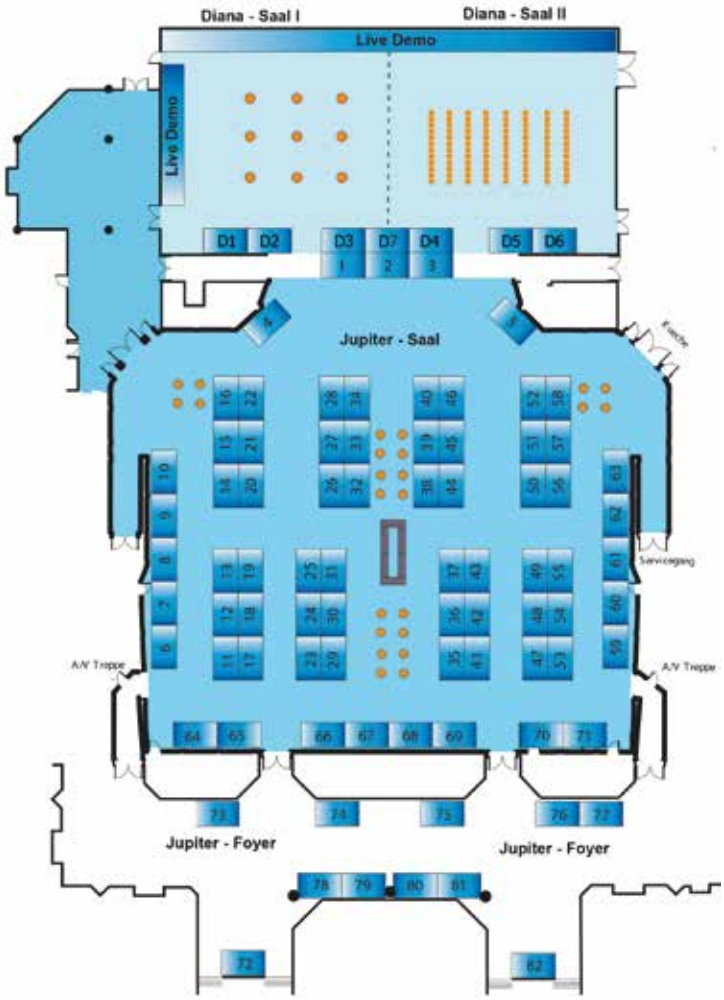
Time	ECA – Data Integrity	ECA – Current Aseptic Technologies	ECA – Bioprocessing	ECA – Integrated Qualification with Suppliers
9:00 h 9:15 h 9:30 h 9:45 h	Key Note Annex 1 Revision – the long and winding road *Dr Bernd Renger, Immediate Past Chair, European Qualified Person Association*			
10:00 h 10:15 h	Break			
10:30 h 10:45 h 11:00 h	Data Integrity from an Inspector's Point of View *Maria Kladi, National Organization for Medicines, Greece*	The evolution of Aseptic Technologies *Dr Friedrich Haefele, formerly Boehringer Ingelheim*	Technological overview: Single-use technologies for intensified and continuous bioprocesses (USP & DSP) *Prof Dr Regine Eibl , Zürcher University of Applied Science*	Future qualification and validation involves suppliers *Gert Moelgaard, ECA Validation Group*
11:15 h 11:30 h 11:45 h	Data Integrity by Design *Stefan Schöttle, Roche Diagnostics*	Challenges in manufacturing high value lyophilized oncologics - a case study *Fabio Gentilini, BSP Pharmaceuticals*	Intensified Downstream Processing through Continuous Manufacture *Pall Biotech* Live Demos	GEP for Suppliers – A Prerequisite for Fast Track Qualification projects? *Ralf Gengenbach, gempex*
12:00 h	Lunch Break			
12:15 h	Virtuelle 3D-Einbausimulation und 3D-Kollisionsprüfung von Maschinen und Anlagen – MehrTec			
12:30 h	Aerosol Alcohol Applicator demonstration – Steris			
12:45 h	Leak testing during prodution of single use equipment – Lippok & Wolf Live Demos			
13:00 h	Prozessindustrie 4.0 - CONEXO – GEMÜ			
13:15 h	Live Derouging mit BERA-DE NT und Deblacking mit BERA-GC HC – Beratherm			
13:30 h 13:45 h 14:00 h	DI as topic of GMP-inspections; an inspector's view *Dr Arno Terhechte, Bezirksregierung Münster*	From design to construction of a new integrated fill&finish facility – combination of proven and new technologies *Dr Gabriele Sabine Roidl, Lonza*	Continuous Biomanufacturing - a GMP inspector's view *Dr Daniel Müller, Local GMP Authority of Baden Württemberg*	Customer-Supplier Cooperation: A project example from Merck Healthcare KGaA *Holger Frey, Merck*
14:15 h 14:30 h 14:45 h	CASE STUDY - A risk based approach for systematic DI-assessments and -mitigation *Hannah Greiner, Epista Life Science*	B+S Multi Dosing System - 3 in 1! *Bausch + Ströbel* Live Demos Single-Use Technology in Aseptic Processing – *Merck* Isolator Technology & RTP Transfer Systems – *Metall + Plastic | Castus*		An effort to build smarter: Transforming Novo Nordisk´s qualification and validation concept to focus on GEP and supplier collaboration *Peter Larsson, Novo Nordisk*
15:00 h	Break	N.N. *MK Versuchsanlagen*		
15:15 h 15:30 h	Live Demo 6 DPTE Transfer Trolley, the mobile transfer platform for smart use with all DPTE Beta solutions – Getinge High pressure washing in the pharma environment – IWT Tecniplast Live Demos			
15:45 h 16:00 h 16:15 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*	Case Study Biosana: Continuous Manufacturing of biosimilar antibodies: a small company's journey to phase 1 clinical studies *Maarten Pennings, Biosana*	Using ECA's Modern Qualification Guide as a pharmaceutical customer *Eva-Maria Baumgartner, Syntacoll*
16:30 h 16:45 h 17:00 h	Data Integrity Compliance Improvement: A Combined Approach to Mitigation *Matthias Runge, Bayer* *Dirk Denecke, Bayer*	EirGen Pharma– How state-of-the-art fill & finish equipment flexibility supports CMO business *Dermot O'Riordan, EirGen*	Case Study Bayer: Continuous Downstream Processing for manufacturing of protein therapeutics *Dr Felix Oehme, Bayer*	Panel Discussion
17:15 h 17:30 h	Discussion	Discussion	Discussion	
18:00 h	Social Event for Congress Delegates, Speakers and Exhibitors			

Content and times subject to change. Updates on the website at www.pharma-congress.com.

Programme – 16 September 2020

ECA –Data Integrity	ECA - Current Aseptic Compliance	ECA – Barrier Systems	Time
Key Note 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
Break			9:45 h 10:00 h
Data Integrity implementation at Curium *Dr Ruud van Stigt, Curium*	Status of Annex 1 revision? *Dr Beate Reutter, Landesamt für soziale Dienste Schleswig-Holstein, Kiel, Germany*	Grey Field Project for Production of Large Scale Bacterial antigen in an Aseptic Environment *Udara Yapa, MSD Animal Health Danube Biotech*	10:15 h 10:30 h 10:45 h
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*	Aseptic processing and filling of a viral vector for gene and cell therapy *Leslie Southam, Oxford Biomedica*	11:00 h 11:15 h 11:30 h
Lunch Break			11:45 h 12:00 h
Autoklavenvalidierung/-qualifizierung leicht gemacht – Ellab			12:15 h
Experience a new generation of transfer hatches live! – Ortner (Live Demos)			12:30 h
Stimmt der Druck im Tank? – Bürkert Fluid Control Systems			12:45 h
Practical Examples found and case studies on how to challenge DI potential issues *Swa Vandeweyer, formerly Janssen Pharmaceutica*	Case Study: Media Fill Design for aseptic Blow Fill Seal Filling *Dr Martin Haerer, Rommelag CMO*	Barrier Systems and Annex 1: GMP inspectors's point of view *Dr Daniel Müller, Local GMP Authority of Baden Württemberg*	13:00 h 13:15 h 13:30 h
Data Integrity in the interaction between business departments and IT as service provider *Thomas Wibbeling, Miltenyi Biotec*	Single Use Bioreactor Platform(SUB) for Microbial Fermentation in a GMP manufacturing facility *Dr Sofia Venceslau, Genibet*	New-Designed Isolator for Aseptic Filling *Quentin Majeau, Hydro Fill*	13:45 h 14:00 h 14:15 h
Break			14:30 h 14:45 h
Data integrity from engineering to operations based on Comos DDMS at Boehringer Ingelheim *Günther Kurta, Boehringer Ingelheim*	Challenges and Opportunities of Aseptic Manufacturing Process Transfers *Dr Martin Schwab, Vetter Pharma-Fertigung*	Vaccines for the World - Insights into Design and Execution of a BSL2 Fill-Finish Facility *Rutger Vandiest, Bavarian Nordic*	15:00 h 15:15 h 15:30 h
Data Integrity and Process Validation: a virtuous circle *Yves Samson, ECA Data Integrity & IT Compliance Interest Group*	Areas of focus for Auditors of Sterile Operations *Hesham Elrayes, B. Braun*	Writing User Requirement Specifications (URS) for Isolator projects *Dr Timo Krebsbach, HHAC Labor Dr Heusler*	15:45 h 16:00 h 16:15 h
Discussion	Discussion	Discussion	16:30 h 16:45 h 17:00 h

Exhibitors of the PharmaTechnica



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☐ **Day 1 (15 September 2020):** I would like to attend the Congress on day 1. I'm primarily interested in the conference:

- ☐ ECA Data Integrity
- ☐ ECA Current Aseptic Technologies
- ☐ ECA Continuous Bioprocessing
- ☐ ECA Integrated Qualification with Suppliers

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☐ **Day 2 (16 September 2020):** I would like to attend the Congress on day 2. I'm primarily interested in the conference:

- ☐ ECA Data Integrity
- ☐ ECA Current Aseptic Compliance
- ☐ ECA Barrier Systems

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