ECA Academy
Your GMP/GDP Information Source

Speakers


Raquel Arenós
INIBSA


Dr Ralf Aubeck
gempex


Dr Detlef Behrens
University of Applied Sciences Gießen / Philips University Marburg


Matthias Buttazoni
Ortner Reinraumtechnik


Dr Patricia Desmaris
Merck Serono


Jill Dietrich
Bausch + Ströbel


Lizar Duhoki
Chemgineering Germany


Martin Frei
Lonza


Bernd Geis
Process [.-ING] Gesellschaft für Projekt- und Qualitätsmanagement


Rainer Glöckler
ten23 health


Dr Friedrich Haefele
Formerly Boehringer Ingelheim Pharma


Dr Stephan Heck
Bipso


Carsten Jasper
Charles River Laboratories


Dr Jean-Denis Mallet
ECA, former Head of the French Inspection Department AFSSAPS


Anton Mangold
Tempris


Christoph Möller
Burgwedel Biotech (MSD)


Steffen Mörler
CSL Behring


Julian Ott
Process [.-ING] Gesellschaft für Projekt- und Qualitätsmanagement


Owen Prichard
Consultant


Londa Ritchey
Pharmalex


Margarida Rosa
GenIbet Biopharmaceuticals


Luigi Scaffidi
Boehringer Ingelheim Pharma


Ralf Wagner
Optima pharma


Patrick Wieland
Bausch + Ströbel


Jörg Zimmermann
Vetter Pharma-Fertigung

European Aseptic Conference

Part of PharmaCongress 2023

28/29 March 2023 | Wiesbaden, Germany

Highlights

- Innovative Therapeutic Options – a Challenge to Aseptic Technologies
- The Evolution of Current Aseptic Technologies
- Case Studies from:
  - Bipso
  - Boehringer Ingelheim Pharma
  - Burgwedel Biotech (MSD)
  - Charles River Laboratories
  - CSL Behring
  - GenIbet Biopharmaceuticals
  - Lonza
  - INIBSA
  - Swissfillon

GMP–PHARMA CONGRESS

This conference is part of PharmaCongress 2023

Objectives

Reasons to attend this conference:

- You will be informed on new regulatory and technological developments in aseptic / sterile manufacturing
- You learn how current GMP and production requirements have to be implemented technologically in sterile manufacture
- 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 manufacture.

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

Moderators

Dr Friedrich Haefele, *formerly Boehringer Ingelheim Pharma*
Jörg Zimmermann, *Vetter Pharma-Fertigung*

Congress Keynotes

28 March 2023
Comprehensive Transformation of DR. KADE's Sites and Supply Chain
Dr Norbert Marquardt, Dr Kade Health Care

29 March 2023
Trends in Aseptic Manufacturing: Questions and demands for Pharma Machine Vendors
Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma

Programme Aseptic Technology 28 March 2023

Implementing of PAT Tool for Lyophilization

Dr Patricia Desmaris, Merck Serono
Dr Frank Deisel, Tempris

- Implementation of a PAT Tool in aseptic conditions with automatic loading in commercial lyophilization

Live Demos

ZETA Sterile Connectors - For Connecting Separate Fluid Paths

ZETA

- ZETA sterile connectors enable GMP-compliant transport in the course of aseptic processing of liquids
- A dry connection between two separate fluid paths is established using connectors and clamps made of stainless steel. The system is characterized by high mechanical stability, pressure load tolerance and temperature resistance.
- Minimizing the risk of contamination when connecting – Steam sterilization possible
- For all common pipe and hose dimensions
- Improved profitability through a reusable system

Tempris PAT Tool for the Implementation of Pharma 4.0 in Lyophilization

Tempris

- Battery- and cable-free real-time Product Temperature Measurement in Lyophilization
- Continuously gather Product Temperature data through entire product lifecycle
- Tempris PAT Tool for the Implementation of Pharma 4.0
- Optimize your Design Space
- Process Automation refined with Real Time Data

CultureOne Single-Use Separation in Bio Pharma

Laval Mid Europe

- Alfa Laval CultureOne is the first separator of its kind.
- The premium range of centrifugal separators is designed for single-use biopharmaceutical applications.
- With proven innovations for gentle product handling and increased yield, CultureOne offers unmatched separation efficiency for high-density cell cultures

Automated Visual Inspection In-Line: 360° Inspection of Vials Seals
Vitronic

- The demonstration will include a live equipment presentation for vial seal inspection
- The audience is guided through the functionalities and set up of the equipment
- The audience will learn about the defect types to be detected with the AVI solution
- Advantages of in-line inspection are discussed
- Practical experience and best practice is share with audience

Continuous Freeze Drying
Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma

- Freeze drying in Food and Pharma
- Market survey
- Batch process lyophilization
- Applications for continuous lyophilization
- Outlook

Energy Saving in Class C Cleanrooms Through Reduced Air Change Rates – a Case Study From a Biotech Company
Dr Detlef Behrens, University of Applied Sciences / Philips University

- Regulatory expectations and typically used air change rates in cleanroom manufacturing
- (Continuous) Control of particles and colony forming units
- Results of a long-term study in various cleanrooms with different air change rates
- Actually required air change rates for class C "in operation" and resulting potential for energy saving

Critical Thinking and Risk Management in Construction Projects as a Means to maximize Value – a Template for new CR Site in Kaarst
Carsten Jasper, Charles River Laboratories

- Critical thinking and risk management are defined and a common understanding is created
- Latest Charles River construction project Kaarst site in Germany is introduced
- Requirements and inputs for the construction project are described with a focus on reagent manufacturing and the clean room facilities processes
- Based on the requirements and inputs the challenge of GMP (customer expectation) vs necessary quality level and costs is worked out
- Critical thinking and risk management are described as levers to design fit-for-purpose solutions and optimize cost-benefit-ratio (value)
- Based on a specific challenge method limitations are described (in this case technical limitations of the building)

What if Final Product Filtration is Not Possible? Challenges and Opportunities of Aseptic Manufacturing for Large Viruses
Margarida Rosa, GenIbet Biopharmaceuticals

- Process Workflow
- Validation protocol that comprises operator validation, gowning considerations, and other points as requested in EudraLex Annex I
- Environmental monitoring strategies
- Materials and/or the equipment - guarantee their correct flow and proper disinfection to prevent contamination and cross-contamination

Programme Aseptic Compliance 28 March 2023

Inspection Readiness in View of Annex 1
Dr Stephan Heck, Bipso
Dr Ralf Aubeck, gempex

- Regulatory background
- Contamination Control Strategy – The new document
- Key aspects of new Annex 1 – Qualification & shop floor excellence
- Authority inspections - local & virtual

Getting the Basics right
Owen Prichard, Consultant

- Viral vaccine manufacture: upscaling, process validation, and sterility testing.
- Supply chain issues and inter-departmental change control procedures.
- Repeated problems for lack of communication

Cross-Contamination: Other Aspects than Cleaning Validation
Dr Jean-Denis Mallet, ECA

- Secondary aspects affecting that risk
- Personnel gowning and personnel behavior
- Materials handling from the synthesis to the compounding
- Equipment not fully designed for the tasks of handling highly potent materials e.g. not preventing all spillages
- Environment, that should be normally free of (any) active substance while a proper aseptic "cascade" can also bring particules away from the point of fill

Airflow Visualization According to New Annex 1
Luigi Scaffidi, Boehringer Ingelheim Pharma

- Regulatory background
- Visualization Methods
- Life Cycle
- Which tracer particles are suitable for cleanrooms?
- Case Study: Interface Airflow Visualization to APS

Sustainable way of flexible Filling – prepared for Future Demands
Martin Frei, Lonza
Patrick Wieland, Bausch + Ströbel

- Optimizing utility consumption
- Minimizing product waste by reducing reject rates
- Saving resources and boosting efficiency
- Maximizing the use of available space
- Could fill-finish systems really be ready for future demands?

Annex 1 and the Related Improvements Out of Machine Vendor Perspective
Dr Fritz Haefele, formerly Boehringer Ingelheim Pharma
Jill Dietrich, Bausch + Ströbel

- Expectation of the pharmaceutical industry
- Impacts on existing equipment
- Challenges for new equipment installations
- Recommendation by a machine vendor how to be prepared for the future

Programme Aseptic Technology 29 March 2023

Preparing the Facility for Extended Global Markets – Case Study
Raquel Arenós, INIBSA
Londa Ritchey, Pharmalex

- Planning, Investments & Timelines
- Global Compliance Considerations & Challenges
- Partnering to supplement Compliance Knowledge
- Change Management - Producing & Improving at the same time
- Sustaining Compliance with Global Regulations

Innovative Ozone Decontamination Process Including Areas of Application and Practical Example
Bernd Geis, Process [.-ING] Gesellschaft für Projekt- und Qualitätsmanagement
Julian Ott, Process [.-ING] Gesellschaft für Projekt- und Qualitätsmanagement
Matthias Buttazoni, Ortner Reinraumtechnik

- Microbiological use of ozone as a decontamination agent
- Technical description of ozone technology in plant construction
  - Ozone generator
  - Required security technology
  - Catalytic decomposition of ozone
- Comparison of decontamination cycle times
- Presentation of the technology using the example of a large-scale material lock in the pharmaceutical environment.
- Effort of process implementation

Flexible Solutions for Different Market Requirements
Rainer Glöckler, ten23 health
Ralf Wagner, Optima pharma

- High potent requirements and technical executions
- Processing of different primary packaging containers
- Machine concepts for different outputs including easy scale-up to production

Relocation of a Capping Machine to an Existing Production Line and Insertion of an Automatic Vial Inspection (AVI)
Christoph Möller, Burgwedel Biotech (MSD)
Lizar Duhoki, Chemgineering

- Relocation of the capping machine
- Integration of capping and filling line
- Face opening for the insertion of the AVI
- Insertion and Installation of AVI

Fast Track Tech Transfer – Experience & Best Practices: Aseptic Filling & Lyo CSL Behring Project
Steffen Mörler, CSL Behring

- Key Challenges
- How to Accelerate
- Best Practice Example
- Team Set up

Speakers

Raquel Arenós, INIBSA
Currently COO and Qualified person for INIBSA, after more than 25 years with INIBSA in Quality and Production leader roles.

Dr Ralf Aubeck, gempex
After 25 year in the pharmaceutical industry since 2017 Principal Consultant at gempex.

Dr Detlef Behrens, University of Applied Sciences Gießen / Philips University Marburg
Lecturer for Quality Management at the Technische Hochschule Mittelhessen (THM - University of Applied Sciences) in Giessen and Phillips-University Marburg.

Matthias Buttazoni, Ortner Reinraumtechnik
Matthias Buttazoni is responsible for technical areas of Ortner Reinraumtechnik, from project management, planning and electrical engineering to installation, commissioning and qualification of complex systems and equipment for the pharmaceutical and life science industries.

Dr Patricia Desmaris, Merck Serono
Pharmacist specialized in biotechnology, expert in Aseptic Processes, F&F, Isolator Technology and CGMPs Compliance.

Speakers

Jill Dietrich, Bausch + Ströbel
Responsible for regulatory compliance regarding GMP in plant construction at B+S since 2022.

Lizar Duhoki, Chemgineering Germany
Lizar Duhoki works as an engineer in a planning consulting company in the pharmaceutical sector.

Martin Frei, Lonza
Martin serves as senior MSAT with focus on freeze drying, sterilisation processes, cleaning strategies and carry over risks and risk assessment regarding product residues in drug products

Bernd Geis, Process [.-ING] Gesellschaft für Projekt- und Qualitätsmanagement
President of the board committee of Engineering Consulting School & Institute of Biochemical Process Engineering.

Rainer Glöckler, ten23 health
CTO

Dr Friedrich Haefele Formerly Boehringer Ingelheim Pharma
Pharma Congress Steering Committee.

Dr Stephan Heck, Bipso
Dr Heck joined Bipso GmbH in 2020 as Site Quality Director. Between 2002 and 2020 he worked in various management positions at Catalent, DSM and Cognis.

Carsten Jasper, Charles River Laboratories
At Charles River he held various positions with increasing responsibility mainly in the field of facility management, equipment qualification and CSV.

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

Anton Mangold, Tempris
Anton Mangold has been an independent entrepreneur, founder and managing director for over 20 years of Tempris GmbH, Holzkirchen/Munich Area, Germany.

Christoph Möller, Burgwedel Biotech (MSD)
Working for MSD for two years as a project engineer of the maintenance Human Health (HH) within the ERVEBO production in Burgwedel.

Steffen Mörler, CSL Behring
Responsible for providing a Center of Excellence to ensure effective project management, Including tools, process, strategy, training programs and teams capability development.

Julian Ott, Process [.-ING] Gesellschaft für Projekt- und Qualitätsmanagement
Lead Project Engineer Pharmaceutical Industry.

Owen Prichard, Consultant
Over 40 years in pharmaceutical manufacturing and quality assurance, from over-the-counter to vaccines and biopharma, with Burroughs-Wellcome, GSK and Genentech. UK, European and US experience.

Londa Ritchey, Pharmalex
Londa Ritchey is currently a Quality Director at PharmaLex with 30 years of experience in pharma/biopharma/ATMP quality assurance emphasizing sterile drug substance and drug product operations.

Margarida Rosa, GenIbet Biopharmaceuticals
Since 2021 as Project Manager at GenIbet.

Luigi Scaffidi, Boehringer Ingelheim Pharma
Since 2012 in quality assurance of a factory filling aseptic inhalation solutions with special focus on qualification, validation, aseptic and hygiene.

Ralf Wagner, Optima pharma
Sales Director for the countries Germany, Austria, Suisse, Portugal and Spain at OPTIMA Pharma.

Patrick Wieland, Bausch + Ströbel
Patrick Wieland is a senior sales professional with more than 10 years of working experience in the pharmaceutical industry.

Jörg Zimmermann, Vetter Pharma-Fertigung
Since November 2019, Jörg Zimmermann is Vice President, Vetter Development Service, External Affairs.

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

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

European Aseptic Conference - Part of PharmaCongress 2023,
28/29 March 2023, Wiesbaden, Germany

☐ **Day 1 & 2 (28/29 March 2023)**
☐ **Day 1 (28 March 2023)**
☐ **Day 2 (29 March 2023)**

☐ **Yes, I would also like to take part in the Social Event on the evening of 28 March 2023.**

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT 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)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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

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

Fees (per delegate, plus VAT)
The one day ticket is available for € 690,- plus VAT, both days for € 1,380 plus VAT. It includes participation in any conference track of PharmaCongress 2023 on that day(s) and the visit of the PharmaTechnica Expo. In addition, lunch and beverages during the tracks and in breaks as well as the social event on the evening of the first congress day, 28 March is included; please mark if you would like to attend the Social Event.

The fee is payable in advance after receipt of invoice.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms close to the CongressCenter. You will receive a room reservation form when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone: +49 (0) 62 21 / 84 44-0
Fax: +49 (0) 62 21 / 84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andreas Mangel (Operations Director) at
+49 (0) 62 21 / 84 44 41, or at
mangel@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49 (0) 62 21 / 84 44 51, or at
strohwald@concept-heidelberg.de