European Aseptic Conference

Part of PharmaCongress 2024

19/20 March 2024
Wiesbaden, Germany

Highlights

- EU GMP Annex 1 – a Challenge to Aseptic Compliance and Technologies?
- The Evolution of Current Aseptic Technologies
- Case Studies from:
  - ABX
  - CinnaGen
  - Letipharma
  - Roche Diagnostics
  - Rommelag CMO
  - Siegfried
  - Vetter Pharma-Fertigung

Speakers

Dr Emad Albarouki | Particle Measuring System, Germany

Dr Friedrich Haefele | Formerly Boehringer Ingelheim Pharma, Germany

Dr Martin Haerer | Rommelag CMO, Germany

Dr Philip Hörsch | Vetter Pharma-Fertigung, Germany

Dr Hiva Hossein Tehrani | CinnaGen, Iran

Dr Constantin Hozsa | Siegfried, Germany

Dr Rita Jacobs-Haage | Vetter Pharma-Fertigung, Germany,

Julia Mathy | Roche Diagnostics, Germany

Franziska Riesen Fuchs | Lonza, Switzerland

Marta Rodríguez Vélez | Letipharma, Spain

Dr Frank Sielaff | Hessian State Office of Health and Care, Germany

Frank Studt | gempex, Germany

Dr Ingrid Walther | Pharma Consulting Walther, Germany

Patrick Wieland | Bausch+Ströbel, Germany

Stephanie Ziesche | ABX advanced biochemical compounds, Germany

GMP–PHARMA CONGRESS

This conference is part of PharmaCongress 2024

ECA Academy
Your GMP/GDP Information Source

GMP–PHARMA CONGRESS

EUROPEAN ASEPTIC CONFERFENCE

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

The revised EU GMP Guideline Annex 1 was published in August 2022 after extensive discussion and came into force mainly in August 2023. Among other things, the consequences of this revised Annex 1 will be presented and discussed with inspectors and industry representatives. The discussion on Annex 1 will be complemented by case studies from pharmaceutical companies on new technological developments in the pharmaceutical production environment.

PROGRAMME 19 March 2024

Compliance in Aseptic Production from a QP-Perspective

Dr Rita Jacobs-Haage, *Vetter Pharma-Fertigung*

- Definition Compliance
- GMP-Compliance
- Confirmation of GMP Compliance as a Qualified Person
- Confirmation of GMP Compliance as a CMO / delineation of responsibilities – Quality Agreements

Industry asks - Annex 1 unfortunately does not answer! - What to do?

Dr Ingrid Walther, *Pharma Consulting Walther*

- From 16 to 59 pages - is everything equivalently clearer?
- The role of Quality Risk Management: Is there room for interpretation?
- The key to understand the guideline is to read it word by word?

Aseptic Production in the Light of the new Annex 1

Dr Frank Sielaff, *Hessian State Office of Health and Care, Germany*

- (New) requirements of Annex 1
- Dealing with the new requirements
- First inspection experiences

Advancing Aseptic Manufacturing: Insights and Best Practices from a Chief Quality Assurance Officer

Dr Hiva Hossein Tehrani, *CinnaGen*

- Pre-Use Post-Sterilization Integrity Testing (PUPSIT)
- Upgrading filling machines to Restricted Access Barrier Systems (RABS)
- Development of a comprehensive contamination control strategy
- Aseptic Process Simulation (APS)

Small Volume sterile Manufacturing– Challenges derived from new GMP Annex 1

Marta Rodríguez-Vélez, *Letipharma*

- Facing the implementation of new GMP Annex 1 in a small volume multiproduct manufacturing site
- Contamination Control Strategy
- Manufacturing technologies (RABS, SUS, automation) in small volume production
- Filtering and PUPSIT in small volume manufacturing

TARGET AUDIENCE

The event is directed at specialists and managers from the pharmaceutical industry as well as at engineers and planners who have to deal with European Annex 1 and current aseptic technologies in clean areas in their daily practice.

MODERATORS

Dr Friedrich Haefele, *formerly Boehringer Ingelheim Pharma*
Frank Studt, *gempex*

PROGRAMME 20 March 2024

Single-Use Design for Small-Volume Filling

Julia Mathy, *Roche Diagnostics*

- Challenge: small-volume filling with small batch sizes and small amount of vials/syringes -> every drop matters; especially for more patient-centralized medicine
- Presentation of possible SUA designs allowing ventilation, blow-down, water flush, etc. to minimize product loss at the start and during the batch
- Full process chain (compounding to filling) will be evaluated, e.g. right DS amount, best filter size, etc.
- Output of the presentation: Ideas on what can be considered if product loss in a single-use chain shall be minimized without impacting the processability of the product

Container Closure Integrity Testing (CCIT) and Biologics – Some Case Studies

Dr Constantin Hozsa, *Siegfried*

- Role of container closure integrity in pharmaceutical industry
- Definition of CCI
- CCI as a concept
- Choosing a CCIT method for your (biologics) drug product
- Product specific considerations, hurdles and pitfalls

Particle Life Cycle Concept

Dr Philip Hörsch, *Vetter Pharma-Fertigung*

- How to implement
- What are the prerequisites?
- What does it tell about the product?
- What can we learn about the visual inspection process and operator qualification?

Implementation and Execution of an active microbial Air Monitoring System into a sterile, radiopharmaceutical Environment

Stefanie Ziesche, *ABX advanced biochemical compounds*
Dr Emad Albarouki, *Particle Measuring System*

- Process technical integration of active microbial air monitoring
  - Communication, control and installation
  - Sterilization cycles
- The use of single use impactor heads for active microbial air monitoring in a sterile environment
- Advantages compared to sampling with classical agar plates and stainless steel impactors or aspects of cleaning, sampling time, safety, false positives and ease of use
- Validation of sampling time with single use impactors and measurement point positioning
- Calibration and maintenance of the system in accordance with current regulations

Case Study: Critical Process Parameters for filling of Sterile Products with BFS Technology

Dr Martin Haerer, *Rommelag CMO*

- Defining of critical quality attributes for the product
- Correlation of Quality attributes with process parameters to guarantee sterility of the product
- Results of a case study with a small volume parenteral container filled with BFS Technology

High Potent Manufacturing Facility: Case Study of Lonza's Challenges with their High Potent Fill&Finish Processes

Franziska Riesen Fuchs, *Lonza*
Patrick Wieland, *Bausch+Ströbel*

- Ensuring operator and product safety
- Maintaining containment
- Controlling cross-contamination during multi-product fill&finish processes
- Implementing robust cleaning processes

SPEAKERS

Dr Emad Albarouki
Particle Measuring System, Darmstadt, Germany
Emad Albarouki is an Application Specialist for Micro & Sterility at Particle Measuring Systems. He joined Particle Measuring Systems in 2023, having previously worked as a Quality Assurance Supervisor for Charles River Laboratory in Germany and as Senior QC Microbiology at Lonza AG.

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

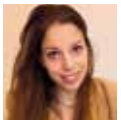
Dr Martin Haerer
Rommelag CMO, Sulzbach Laufen, Germany
Since more than 30 years in Pharma industry with experience in sterile filling, Qualified person since 20 years, Regulatory officer BFS IOA Association, Co-author TR 77.

Dr Philip Hörsch
Vetter Pharma-Fertigung, Ravensburg, Germany
Between 2004 and 2015 as Project Manager Microbiology, Team and Site Manager Quality Operations at Vetter. Since 2015 Director Quality Assurance for (Process-) Validation, Risk Management, Trending, IT-Systems, IPC/Visual Inspection Systems and Specification Management Packaging Materials.

Dr Hiva Hossein Tehrani
CinnaGen, Karaj, Iran
Hiva is a pharmacist currently working at CinnaGen, a renowned biopharmaceutical company, where she has been a dedicated team member since 2015. Currently she is in the position of Chief Quality Assurance Officer.

Dr Constantin Hozsa
Siegfried, Hameln, Germany
Dr Constantin Hozsa is a project manager for formulation and process development at Siegfried's Hamel (Germany) based R&D-department. His responsibilities include the introduction of new Container Closure Integrity Test (CCIT) systems and the development of new CCIT methods. He is also responsible for the site's Annex 1 compliant CCI strategy.

Dr Rita Jacobs-Haage
Vetter Pharma-Fertigung, Ravensburg, Germany
After studying pharmacy, Dr Jacobs-Haage held various positions in clinics and pharmaceutical companies. Since 2016, she has been working as a QP at Vetter.



Julia Mathy
Roche Diagnostics, Mannheim, Germany
Julia joined Roche in 2021 as a process engineer. She is responsible for tech transfers, new products, and new technologies. Her main topics are Single-Use Systems, End-to-end processing, Primary packaging, and robotic filling.

Franziska Riesen Fuchs
Lonza, Stein, Switzerland
Operations Head for the new sterile Drug Product Manufacturing facility in a Capital investment project for sterile Drug product manufacturing, warehouse and quality control unit.

Marta Rodríguez Vélez
Letipharma, Tres Cantos, Spain
More than 20 year' experience in pharmaceutical industry, focused on quality assurance and regulatory compliance.

Dr Frank Sielaff
Regional Authority, Darmstadt, Germany
GMP-Inspector at the Regierungspräsidium Darmstadt with the focus on Inspection of drug manufacturers and laboratories in Germany and countries outside of the EU. Before joining the GMP-inspectorate Frank was several years employed in the pharmaceutical industry as Head of Quality Control and as Qualified Person.

Frank Studt
gempex, Germany
Managing Director.

Dr Ingrid Walther
Pharma Consulting Walther
Chairman of the ECA Working Group on Annex 1.

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

Stephanie Ziesche
ABX advanced biochemical compounds, Radeberg, Germany
Expert in process and product Validation, GMP and Quality Assurance.

The guiding theme of the GMP PharmaCongress 2024 on 19/20 March will be „users sharing challenges and solutions in practice". Therefore, benefit from your colleagues' experience and from the direct information exchange at the GMP PharmaCongress & GMP PharmaTechnica 2024.

The Conference Tracks

As a participant you can switch between any of the **11 conference tracks** any time and also visit the PharmaTechnica Expo with more than 110 international exhibitors.

The GMP PharmaCongress Conference Tracks	19 March 2024	20 March 2024
Non-Sterile Products – Challenges in Manufacturing & Quality	✓	n.a.
GMP – Green or Good Manufacturing Practice?	✓	n.a.
Packaging/Packaging Materials – Challenges & Solutions	n.a.	✓
European Aseptic Conference – Technology	✓	✓
Trends in Barrier Systems & Robotics	✓	✓
Modern Cleanroom Technology	✓	✓
Digitalisation & Artificial Intelligence	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Lyophilization – Modern Techniques & New Requirements	✓	✓
ATMPs – Hurdles & Achievements in Quality and Safety	✓	✓
Vaccines – Advantages & Challenges in Manufacturing	✓	✓
GMP PharmaTechnica Expo	✓	✓

Keynote on 19 March 2024

The CEPI Project – 40 Countries – 1 Billion Euros for Vaccines

Dr Guido Dietrich, *CEPI*

Do you know the worldwide importance of CEPI? And why is this so important for everyone working in pharmaceutical production? Our first keynote will address a very important new development. More than 40 countries, several non-governmental organizations and the European Commission are involved in the **Coalition for Epidemic Preparedness Innovations (CEPI)**.

What is the goal?
The goal of CEPI is to develop, produce and distribute a vaccine as quickly as possible in the event of the next global pandemic, i.e. within 100 days.

What is the current budget?
For the first 5 years alone, a budget of one billion euros has been made available.

In the Live Demo Area in the PharmaTechnica Expo hall you will benefit from the exhibitors' demonstrations – presenting their latest technology, products and services. Take advantage of these live performances – and get to feel and experience their products. For a list of all companies exhibiting at PharmaTechnica, please see the exhibitor list and plan on the website at **www.pharma-congress.com**.

Exhibitor	Stand	Live Demo
boTec	A 7	TBN
MKVersuchsanlagen	A 12	TBN
Ellab	A 16	TBN
Bausch+Ströbel	A 33	OMNIA - Boost your processes and step closer to your pharmaceutical plant of the future.
PHARMAPLAN	A 37	Accelerated Design Decisions enabled by Digital Twins
Quascenta Pte	B 6	Using an Intelligent Lifecycle-Based Solution for Streamlined Product Tracking, Design Optimization, Collaboration, and Reporting
ZETA	B 12	TBN
IWT / Tecniplast	B 15	High pressure cleaning in pharmaceutical production. Advantages, challenges, sustainability and savings
MBV	B 20	TBN
Emerson Automation Solutions	B 22	TBN
Atec Steritec	B 28	Safe & Sterile Transfer with Minimal Operator Intervention
REA Elektronik	B 29	Experts in Printing and Code Verification of pharmaceutical and medical-device packaging (f.e.UDI/MDR)
Friedrich Sailer	B 31	Shining Solutions: Live Demo of Cutting-Edge Stainless Steel Cleanroom Equipment
Merck	B 32	Annex 1's "Specific Risks Associated with Single-Use Systems"
Particle Measuring Systems	C 7	Facility Monitoring Systems
Yokogawa	C 9	Flow Imaging using FlowCam for High Performance Products to warrant constant excellent Quality

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Registration Form:
(06221) 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

Congress Dates
Tuesday, 19 March 2024, 09.00 - 18.00 h
Wednesday 20 March 2024, 09.00 - 17.00 h
Registration
Tuesday & Wednesday, 19/20 March 2024, 08.00 - 09.00 h

Fees
The one day ticket is available for € 690,- plus VAT, both days for € 1,380.- plus VAT. It includes participation in any track on that day 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, 19 March is included; please mark if you would like to attend the Social Event. The fee is payable in advance after receipt of invoice.

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

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

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 2024

19/20 March 2024, Wiesbaden, Germany

☐ Day 1 & 2 (19/20 March 2024)
☐ Day 1 (19 March 2024)
☐ Day 2 (20 March 2024)

☐ Yes, I would also like to take part in the Social Event on the evening of 19 March 2024.

☐ Mr ☐ Ms ☐ Mx ☐ Dr

First name, Surname

Company

Department

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

Street/P.O. Box

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 HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation 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.

WH/01122023