# GMP–PHARMA CONGRESS

#sharing challenges and solutions in practice

19/20 March 2024, RheinMain CongressCenter Wiesbaden

**11**
Conferences

**100+**
Speakers

**110+**
Exhibitors

European Aseptic Conference
Trends in Barrier Systems & Robotics
Modern Cleanroom Technology
Non-Sterile Products – Challenges in Manufacturing and Quality
Digitalisation & Artificial Intelligence
Packaging/Packaging Materials – Challenges and Solutions
GMP for Pre-Filled Syringes (PFS)
Lyophilization – Modern Techniques and New Requirements
ATMPs – Hurdles & Achievements in Quality and Safety
Vaccines – Advantages and Challenges in Manufacturing
GMP – Green or Good Manufacturing Practice?

Please scan the code to read the **full agenda and details** of the GMP PharmaCongress or to **register directly online** – or visit www.pharma-congress.com

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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.

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| Trends in Barrier Systems & Robotics | ✓ | ✓ | 12/13 |
| Modern Cleanroom Technology | ✓ | ✓ | 14/15 |
| Digitalisation & Artificial Intelligence | ✓ | ✓ | 16/17 |
| GMP for Pre-Filled Syringes (PFS) | ✓ | ✓ | 18/19 |
| Lyophilization – Modern Techniques & New Requirements | ✓ | ✓ | 20/21 |
| ATMPs – Hurdles & Achievements in Quality and Safety | ✓ | ✓ | 22/23 |
| Vaccines – Advantages & Challenges in Manufacturing | ✓ | ✓ | 24/25 |
| GMP PharmaTechnica Expo | ✓ | ✓ | |

## Fees

€ 690,- for the one day ticket plus VAT. These one day tickets allow you to follow any track offered that day (you can also switch between the tracks any time). They include a lunch and beverages during the tracks and in breaks as well as the free visit of the PharmaTechnica Expo and the social event on the evening of the first congress day. Charges are payable after receipt of invoice. Please note that due to the special fees for the congress, ECA membership discounts are not applicable.

## Exhibition

Parallel to the tracks there will be the PharmaTechnica Expo. Take advantage of this opportunity to get to know new technologies, products and services at the stands of the more than 110 international exhibitors.

## Location

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

## Contacts – Conference Tracks

**For questions regarding the content of the tracks:**

Non-Sterile Products – Challenges in Manufacturing & Quality | GMP – Green or Good Manufacturing Practice?
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European Aseptic Conference | Trends in Barrier Systems & Robotics | Digitalisation & Artificial Intelligence
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Packaging/Packaging Materials – Challenges & Solutions | GMP for Pre-Filled Syringes (PFS) | Lyophilization – Modern Techniques & New Requirements
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ATMPs – Hurdles & Achievements in Quality and Safety | Vaccines – Advantages & Challenges in Manufacturing
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## Contact – Organisation

**For questions regarding the organisation:**
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## Organiser

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## Please note

**Exhibition Visit:** The PharmaTecnica Expo 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 visit. The visit of the exhibition does not entitle you to also attend any of the tracks.

**Congress Materials:** Please note that there will not be any printouts at the Congress. Instead you will receive all available presentations prior to the Congress as Downloads.

**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.

## Keynote 19 March 2024

### Manufacturing of Pandemic Vaccines – Manufacturing & Supply Solutions Enabling the Delivery of Large Numbers of Vaccine Doses

**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.

## Keynote 20 March 2024

### Presentation by the Wallhäußer Innovation Award Winner

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**.

| Day | Time | Exhibitor | Stand | Live Demo |
|---|---|---|---|---|
| 19 March 2024 | 10.00–10.15 h | Ellab | A 16 | Self mapping made easy |
| | 10.15–10.30 h | boTec | A 7 | Optimized planning and operation of pharmaceutical storage and distribution systems |
| | 11.15–11.30 h | Bausch+Ströbel | A 33 | OMNIA - Boost your processes and step closer to your pharmaceutical plant of the future |
| | 11.30–11.45 h | Merck | B 32 | Annex 1's "Specific Risks Associated with Single-Use Systems" |
| | 11.45–12.00 h | Cytiva | C 5 | Point-of-use leak testing of single-use systems |
| | 12.30–12.45 h | MK Versuchsanlagen | A 12 | State of the art testing of barrier systems |
| | 12.45–13.00 h | Innerspace | B 14 | Aseptic Training with Virtual Reality |
| | 13.00–13.15 h | MBV | B 20 | MBV MAS-100 ISO – Microbial Air Sampler |
| | 15.00–15.15 h | ZETA | B 12 | Intelligent solution for passing single-use tubes through cleanroom walls |
| | 15.15–15.30 h | Friedrich Sailer | B 31 | Shining Solutions: Live Demo of Cutting-Edge Stainless Steel Cleanroom Equipment |
| | 15.30–15.45 h | Particle Measuring Systems | C 7 | Facility Monitoring Systems |
| 20 March 2024 | 09.45–10.00 h | PHARMAPLAN | A 37 | Virtual Pharma Campus |
| | 10.00–10.15 h | Emerson Automation Solutions | B 22 | Real-Time Scheduling and Production Optimization |
| | 10.15–10.30 h | Yokogawa | C 9 | Predict, Prevent, Perform: A Proactive Approach to Asset Health in the Pharmaceutical Industry |
| | 12.00–12.15 h | REA Elektronik | B 29 | Experts in Printing and Code Verification of pharmaceutical and medical-device packaging (f.e.UDI/MDR) |
| | 12.15–12.30 h | IWT / Tecniplast | B 21 | High pressure cleaning in pharmaceutical production. Advantages, challenges, sustainability and savings |
| | 12.30–12.45 h | Quascenta Pte | B 6 | Using an Intelligent Lifecycle-Based Solution for Streamlined Product Tracking, Design Optimization, Collaboration, and Reporting |
| | 12.45–13.00 h | Kneat Solutions | C 12 | Kneat Gx Demo |

Live Demos and Times Subject to Change

GMP–PHARMA CONGRESS

# SPEAKERS

The following more than 100 speakers from industry and authorities already have confirmed their participation (constantly updated):

**Dr Andreas Aemissegger**
Bachem, Switzerland, *Head Oligo Capex.*

**Jyotsna Agnihotry**
Flavine Europe, Germany, *Head of QA and Regulatory Affairs.*

**Dr Emad Albarouki**
Particle Measuring Systems, Germany, *Microbial Application Specialist.*

**Ib Alstrup**
Danish Medicines Agency, DMA, Denmark, *GxP IT Medicines Inspector.*

**Pranvera Apostoli**
Profarma, Albania, *QA and RA Manager.*

**Henning Austermann**
Siegfried, Germany, *Head of Engineering.*

**Dr Alexander Bachmann**
Pharmaceutical Consultancy Dr Bachmann, Germany, *CEO & Founder.*

**Dr Andrea Bauer**
Andrea Bauer Consulting Quality (ABC&Q), Germany, *Consultant.*

**Dr Annika Bernsdorf**
GlaxoSmithKline Biologicals, Germany, *Sterility Assurance Expert & Qualified Person.*

**Maria Luisa Bernuzzi**
MesaLabs, France, *Product and Application Engineer.*

**Thomas Beutler**
GEA, Germany, *Head of System Engineering and Special Project Management.*

**Dr Carsten Börger**
Valicare, Germany, *Senior GMP Project Manager.*

**Bianca Bohrer**
PSM, Schiffweiler, Germany, *CEO.*

**Dr Thomas Brinz**
Syntegon, Germany, *Director Pharma Services Waiblingen.*

**Markus Burkert**
Syntegon, Germany, *Product Manager Sustainability.*

**Eni Bushi**
Profarma, Albania, *Validation Manager.*

**Dr Ursula Busse**
Tigen, Switzerland, *Head of Regulatory Affairs.*

**Francis Carroll**
West, Ireland, *Technical Specialist.*

**Pasquale Cataldo**
Roche Diagnostics, Germany, *Innovation Project & Lab Lead.*

**Dr Göran Crucius**
Cilag / Janssen – Pharmaceutical Company of Johnson & Johnson, Switzerland, *Senior Operations Manager Transformational Projects & Business Support.*

**Sergio Cuevas Luján**
Boehringer Ingelheim, Spain, *Packaging Materials Engineer.*

**Jean-François Decoster**
UCB, Belgium, *Head of Primary Packaging Development.*

**Yvonne Duckworth**
CRB, Conshohocken, USA, *Fellow of Digital Technology.*

**Dennis Dürr**
Roche Diagnostics, Germany, *Process validation engineer.*

**Petra Falb**
AGES, Austrian Agency for Health and Food Safety.

**Nikolaus Ferstl**
Facility Engieering Services, Germany, *Managing Director.*

**Alicja Fiedorowicz**
Dark Horse Consulting, UK, *Senior Consultant.*

**Dr Tino Galgon**
Lyocontract, Germany, *Managing Director.*

**Dr Rainer Gnibl**
*Government of Upper Bavaria, Germany, GMP Inspector.*

**Katharina Golly**
Novartis, Switzerland, *Senior Expert Engineering.*

**Xavier Gómez**
Telstar, Spain, *Lyophilization Product Manager.*

**Dr Marcel Goverde**
MGP Consulting, Switzerland, *General Manager.*

**Dr Martin Haerer**
Rommelag CMO, Germany, *Senior Director R&D / Qualified Person.*

**Dr Sabine Hauck**
ECA ATMP Interest Group, Germany, *Chair.*

**Dr Armin Hauk**
Sartorius Stedim Biotech, Germany, *Principal Scientist.*

**Frank Heck**
CSL Behring, Germany.

**Dr Juliane Heilig**
CMT Cellex Manufacturing Transports and Logistics, Germany, *QP.*

**Martin Heitmann**
d-fine, Germany, *Senior Manager.*

**Dr Ulrike Herbrand**
Charles River Laboratories, Germany, *Scientific Director Global in vitro Bioassays.*

**Frank Hessler**
Schlafender Hase, Germany, *Managing Director.*

**Dr Philip Hörsch**
Vetter Pharma-Fertigung, Germany, *Director QA - Validation/Risk Management/Trending.*

**Manfred Holzer**
Skan, Switzerland, *Strategic Product Manager ebeam Technology.*

**Dr Hiva Hossein Tehrani**
CinnaGen, Iran, *Chief Quality Assurance Officer.*

**Dr Constantin Hozsa**
Siegfried, Germany, *Project leader formulation development.*

**James Humphrey**
Croda Pharma, UK, *Research and Technology Specialist.*

**Dr Bernhard Illes**
Microcoat Biotechnologie, Germany, *Project Manager.*

**Dr Rita Jacobs-Haage**
Vetter Pharma-Fertigung, Germany, *Qualified Person.*

**Christa Jansen-Otten**
West, Germany, *Director of Technical Product Development.*

**Kenan Kanmaz**
Optima pharma containment, Germany, *Technical Sales Manager.*

**Dr Markus Keller**
Fraunhofer Institute for Manufacturing Engineering and Automation (IPA), Germany, *Project Manager.*

**Robert Kibele**
groninger & co., Germany, *Product Manager.*

**Harald Kiesel**
Skan, Switzerland, *Strategic Product Manager.*

**Rashid Idd Kihwelo**
Kairuki Pharmaceuticals, Tanzania, *Senior Quality Control Microbiologist.*

**Dr Anne-Grit Klees**
Merck, Germany, *Global Product Manager.*

**Christian Klinger**
Roche, Germany, *Senior Expert Process Science / Manufacturing Science and Technology.*

**Dr Ulrich Köllisch**
GxP-CC, Germany, *Partner.*

**Dr Johannes Krämer**
CSL Behring, Germany, *Global Head of Maintenance & Utilities.*

**Dr Lars Kreye**
Boehringer Ingelheim Pharma, Germany, *Head of Regulatory Compliance.*

**Lenz Kunath**
Merck Healthcare, Germany, *E&T Director.*

**Doris Laçej**
Profarma, Albania, *Head of Sterile LVP Production.*

**Pirkko Lahti**
Orion, Finland, *Senior Development Manager.*

**Dr Tobias Ladner**
Roche Diagnostics, Germany, *Dynamic Team Lead.*

**Prof Alf Lamprecht**
University of Bonn, Germany, *Professor for Pharmaceutical Technology and Biopharmacy.*

**Dr Benjamin Ledermann**
GEA, Germany, *Expert for freeze drying technology. of the Pharma Congress Steering Committee.*

**Rolf Lenhardt**
Teclen, Germany, *Founder and Managing Director.*

**Susana Lima**
Bial Portela, Portugal, *Environment Specialist.*

**Galit Lisaey**
Gal.IT Data Integrity Consulting, Israel, *Director and Founder.*

**Faye Litherland**
Fluor Limited, UK, *Director, Process/Specialty Engineering .*

**André Lourenço**
NNE, Denmark, *HVAC & Cleanroom Specialist Engineer.*

**Dr Jean-Denis Mallet**
Pharmaplan, France, *Former head of the French Inspection Department AFSSAPS.*

**Dr Natalia Markova**
Malvern Panalytical, UK, *Head of Science.*

**Julia Mathy**
Roche Diagnostics, Germany, *Process Engineer.*

**Sandra Meier**
Charles River Laboratories, Germany, *Scientific Officer for R&D Team/Study Director Processvalidation.*

**Didier Meyer**
DMCompliance, France, *Consultant.*

**Anette Mörbel-Witte**
Sanofi-Aventis Deutschland, Germany, *Head of Projects & Planning SFB&O Engineering.*

**Dr Sven Alexander Moritz**
Sanofi-Aventis Deutschland, Germany, *Global Quality Strategy.*

**Carsten Moschner**
CMC3, Germany.

**Dr Daniel Müller**
Local GMP Authority of Baden Württemberg, Germany, *Head of GMP Inspectorate.*

**Stefan Münch**
Körber Pharma Consulting, Germany, *Vice President of Validation and Qualification.*

**Heide Nagel**
Novartis Pharma Stein, Switzerland, *Senior QA Expert.*

**Dr Veronika Nindl**
VTU Engineering, Austria, *Senior Manufacturing Science and Technology Engineer.*

**Dr Wenzel Novak**
Gerresheimer Bünde, Germany, *Senior Global Director Business Development.*

**Andreas Nuhn**
D&B Pharmadesign, Germany, *Managing Director.*

**Dr Jan Oberländer**
GfPS, Germany, *Head of Packaging Testing.*

**Dr Nicole Paland**
Minerva Biolabs, Germany *Head of Product Development.*

**Cecilia Pierobon**
STERIS Life Sciences, Germany, *Technical Service Manager.*

**Ana Cláudia Pinho**
Bial Portela, Portugal, *Senior Manager Sustainability.*

# SPEAKERS

**Nikhil Rautela**
USP, Switzerland, *Senior Scientific Affairs Manager- Biologics.*

**Dr Johannes Reich**
Microcoat Biotechnologie, Germany, *General Manager.*

**Marta Rodríguez-Vélez**
Letipharma, Spain, *Quality Assurance.*

**Jinesh Sadalge**
Novartis, Austria, *Senior Expert Engineering.*

**Yves Samson**
Kereon, Switzerland, *Founder and Chairman.*

**Dr Helen Sauter**
Vetter Pharma-Fertigung, Germany, *Director QA – Sterility Assurance/Lab Operation/Training systems.*

**Luigi Scaffidi**
Boehringer Ingelheim Pharma, Germany, *Manager Qualification / Validation / Aseptic / Hygiene.*

**Matthias Schaar**
Novartis, Switzerland, *Lead Qualification & Infrastructure team.*

**Sebastian Scherr**
LTS Lohman Therapie-Systeme, Germany, *Head of Process Development – MAP CDMO.*

**Dr Max Scheible**
Vetter Pharma-Fertigung, Germany, *Team Leader AVI Projects, Development Service*

**Katharina Schlereth**
Labor LS, Germany, *Division Head, Microbiolo-gical Testing of Sterile Products.*

**Dr Arne Schröder**
Vetter Pharma-Fertigung, Germany, *Head of Production in the area of manufacturing and filling of sterile drug products.*

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

**Marsha Steed**
Steed MicroBio, USA, *Founder and CEO.*

**Erik Steffensen**
Spot-on Pharma Consulting, Denmark, *CEO.*

**Prof Dr Sven Stegemann**
DWI – Leibniz-Institut für Interaktive Materialien e.V., Germany, *CEO.*

**Frank Studt**
gempex, Germany, *Managing Director.*

**Dr Jörg Stüben**
Boehringer Ingelheim International, Germany, *Head of Regulatory Information Management and Senior Expert.*

**Antoine Toussaint**
GlaxoSmithKline Vaccines, Belgium, *Global Expert Sterility Assurance.*

**Dr Mohamad Toutounji**
Molgenium, Germany, *CEO & Founder.*

**Dr Andrea Traube**
KyooBe Tech, Germany, *CEO.*

**Ioannis Tsiagkas**
Pharmathen, Greece, *Technical/Quality Agreements Specialist.*

**Ruben van der Galiën**
GE HealthCare, Netherlands, *Qualified Person.*

**Dr Ingrid Walther**
Pharma Consulting Walther, Germany, *Chairman of the ECA Annex 1 Task Force*.

**Dr Andrea Weiland-Waibel**
ExplicatPharma, Germany, *Founder and Managing Director.*

**Patrick Wieland**
Bausch+Ströbel, Germany, *Global Lead Business Development.*

**Dr Florian Witte**
Boehringer Ingelheim Pharma, Germany, *Head Quality Assurance Unit.*

**Alistair Wotherspoon**
CRB, Switzerland, *Senior Process Utilities Engineer.*

**Stephanie Ziesche**
ABX advanced biochemical compounds, Germany, *Manager Radiopharmacy Radiochemistry and R&D.*

## OBJECTIVES

This year, the first part of the conference track will deal with topics such as automation, statistical process control or self-inspection, and the second part will deal with cleaning validation and microbiological issues. Current and modern approaches for identifying sampling points in the non-sterile area (grid-line approach) will be presented, and topics such as risk mitigation versus microbial testing will also be discussed.

## BACKGROUND

Even though the focus today is strongly on the new Annex 1 and the various sterile drugs, non-sterile drugs still represent the most common dosage form, especially tablets with a share of more than 50%. Solids in particular often represent cost-effective dosage forms. They have good stability and open up adjustable options for active ingredient release.

But the various forms of non-sterile drugs also face a number of challenges in manufacturing, quality assurance and quality control. Continuous processing, procurement of production equipment and validation issues related to manufacturing play a role as well as modern validatable purification or microbial requirements e.g. regarding modern risk assessment in bioburden or Burkholderia cepacia complex. Questions of monitoring are also of interest again and again.

## TARGET AUDIENCE

This conference track is aimed at all persons in the field of manufacturing, quality assurance and quality control who have to deal with the problems of the non-sterile manufacture of medicinal products or their active and starting materials.

## MODERATOR

Dr Marcel Goverde, *MGP Consulting*

### Fully Automated and DoE-Based Development of an Oral Solid Dosage Form

Dr Thomas Brinz, *Syntegon*

- Planning of all trials using Design-of-Experiments
- Automated execution of all experiments and analysis of the results
- How to reach Based on the automation of all development steps a high throughput and short development time

### Use and Implementation of SIX sigma and SPC (Statistical Process Control) Cp and CpK to improve our Routine Production Process throughout finding the Problems

Pranvera Apostoli, *Profarma*

- Capture of CPP values as part of APR (Annual Product Review) values for 300 generics - captured for final product and process steps
- Use of SPC, IMR and trend charts
- Analysis of Cp and CpK values and assessment of stability
- Root Cause Analysis in Cases of Instability

### EU-GMP Inspection: Inspector's hot topics

Dr Rainer Gnibl, *Government of Upper Bavaria, Germany*

- Essential requirements in inspection
- Which systems are critical?
- Knowledge management
- Do's & Don'ts in inspection

### Cleaning Validation in Pharmaceutical Manufacturing Industry

Eni Bushi, *Profarma*

- Regulatory requirements for cleaning validation
- Cleaning validation program
- Sampling procedure
- Establishment of limits

### Modern Approach for Identifying Sampling Points in the Non-Sterile Area (grid-line Approach)

Dr Marcel Goverde, *MGP Consulting*

- FMEA or HACCP or Risk Assessment?
- Can a gridline approach also be used for non-sterile areas?
- Application in practice

### USP chapter <1115> – Industrial Implementation

Dr Marcel Goverde, *MGP Consulting*

- Development of a FMEA using USP <1115>
- Practical implementation for a filling line (non-sterile drug product)
- Lessons learned

### A Case of *Burkholderia cepacia* Complex in Non-Sterile Manufacturing; Challenges in Isolation, Identification and Product Recalls

Rashid Idd Kihwelo, *Kairuki Pharmaceuticals*

- What is Burkholderia cepacia Complex (Bcc)
- Taxonomy and diversity of BcBcc contamination in non-sterile manufacturing
- Challenges in isolation, Identification and the new USP chapter <60>
- Product recalls of non-sterile products and measures to be taken to prevent Bcc contamination

## OBJECTIVES

This conference track will take a closer look at and discuss the possibilities of sustainability, environmental thinking and energy saving also under GMP conditions. The extent to which regulatory requirements, quality demands and modern sustainability requirements fit together will also be a topic of discussion. Case studies will be used to present practical implementations and highlight improvement measures.

## BACKGROUND

In the past, compliance with quality requirements and safety aspects in the manufacture of drugs, active ingredients, etc. was often the primary focus. Environmental aspects, energy costs, water consumption and the like were usually not at the top of the priority list. This has changed in recent years - under the influence of climate change, rising energy prices, increased transport costs and scarcity of raw materials. Buzzwords like Sustainability or Green GMP are heard more and more often. On the one hand because of the increasing environmental problems and on the other hand because of the rapidly rising costs for energy, water and raw materials. The challenge is often how to combine the requirements of GMP and sustainability.

## TARGET AUDIENCE

This conference track is aimed at all persons in the field of manufacturing, facility management, quality assurance and quality control who have to deal with the problems of sustainability aspects under the regulation of GMP.

## MODERATOR

Dr Johannes Reich, *Microcoat Biotechnologie*

### Sustainability and GMP – Contradictive or supportive? How can Sustainability Aspects been built in GMP Requirements

Dr Andrea Bauer, *ABC&Q*

- Expectations of stakeholders
- Embedding sustainability in entire product life cycle
- Supporting and contradicting expectations and requirements

### Reading the EU-GMP Guide with green Glasses

Dr Jean-Denis Mallet, *Former head of the French Inspection Department AFSSAPS, Pharmaplan*

- The Green target
- Type of actions that really be deemed Green
- Reading the guide with Green Glasses : the main promising points
- How much Green action will be impacting the marketing authorization dossier ?
- Conclusion

### Does Sustainability stand only for Green GMP?

Ana Cláudia Pinho, *Bial Portela*

Susana Lima, *Bial Portela*

- What does Sustainability mean – Environment Saving? Green?
- Other Aspects
  - Social responsibility
  - Economic viability
  - Ethical considerations

### Sustainable and Energy-Efficient Planning and Construction of a Laboratory and Production Facility

Dr Johannes Reich, *Microcoat Biotechnologie*

- Planning of a new Laboratory and Manufacturing Complex
- Solar and water - energy generation and storage
- Heating and cooling - modern possibility of sustainability
- Pros, cons and pitfalls
- Costs and ROI

### Sustainability – HVAC Optimization Program at Merck Healthcare KGaA with significant Energy Savings

Lenz Kunath, *Merck Healthcare*

- Challenge “regulated” air change rates, use other criteria to determine room cleanliness
- Reduce permanent air change rates
- Reduce air change rates during non-productive times
- Challenges executing the program

### How to reduce Carbon & Water Footprint in clean Utility Systems

Alistair Wotherspoon, *CRB*

- Reducing the carbon burden of aseptic products is an uphill battle for manufacturers still latching on to WFI by distillation
- In 2017, the European Pharmacopeia joined the majority of pharmacopeias around the world allowing for alternative methods of generating WFI – methods far less demanding on energy and water than that of distillation
- It’s time to reevaluate the WFI systems
- Industry is poised to make the move to benefit the environment and find resiliency against energy uncertainty
- User case from an ongoing project at Lonza

### Sustainability in Pharma – how a Company can achieve $CO_2$ net zero Goal

Henning Austermann, *Siegfried*

Markus Burkert, *Syntegon*

- Siegfried's goal of climate neutrality
- Projects and activities - from green electricity to district steam and heating
- $CO_2$ analysis and optimization of machine park
- Further prospects and potentials, e.g. sustainable raw materials

## OBJECTIVES

In this conference you will learn which requirements apply for packaging material and pre-sterilized material (e.g., ready-to-use, ready-to-sterilize). You will get to know relevant GMP aspects for packaging materials (e.g., vials, stoppers) that influence the quality of the final product. In addition, practice-oriented presentations and case studies will guide you through the relevant requirements on qualification / validation, and controls for packaging materials, including text control.

## BACKGROUND

Currently there is a growing demand in the development of packaging materials (e.g. ready-to-fill, ready-to-use, sterile clean filling) for several enhanced Biotech applications. However, new GMP requirements for the sterile packaging material apply with the revised EU GMP Annex 1. In addition, there are various other requirements like testing on E&Ls, distribution testing and text and code control (e.g., Data Matrix codes required for serialization purposes).
This event will therefore deal with the current discussions and trends in the packaging operations and packaging materials:

- Regulatory Challenges & GMP requirements
- Primary and Secondary Packaging
- Text and Code Control
- Packaging Challenges in Aseptic / Sterile Manufacturing
- Microbiological Control
- Distribution Testing

The presentations will be provided in a practice-oriented way from the different viewpoints of suppliers of packaging materials / devices / services, and the pharmaceutical industry.

## TARGET AUDIENCE

This event is designed for employees working in the pharmaceutical industry (including drug device combination products), for suppliers of packaging materials & devices and to all who have to deal with the manufacture, control and release of packaging materials. The key areas are

- Sterile Production
- Packaging material / Medical Devices
- Manufacturing / Processing / Assembling
- Quality Control
- Quality Assurance

## MODERATOR

Dr Marcel Goverde, *MGP Consulting*

### Primary and Secondary Packaging of Drug Substances

Jyotsna Agnihotry, *Flavine Europe*

- Primary and secondary packaging in the Biopharmaceutical industry
- Types of primary packaging
- Single Use Systems (SUS)
- Secondary packaging for Biopharmaceuticals
- Packaging of Biopharmaceuticals for safe storage and shipping (e.g., correct packaging to enable efficient filling, freezing, and transportation)

### Regulatory demands / Challenges in CCS of Injections

Pirkko Lahti, *Orion*

Suitability of container system:

- Protection
- Safety
- Compatibility
- Performance

### Packaging Materials Challenges in Aseptic / Sterile Manufacturing

Sergio Cuevas Luján, *Boehringer Ingelheim*

- Packaging materials for aseptic manufacturing: a complex packaging for a complex process
- Safety, efficiency, sustainability in packaging design and packaging materials for aseptic processes
- Packaging materials validation for aseptic manufacturing
- New trends in packaging materials for aseptic manufacturing

### Microbiological Control of Packaging Materials

Dr Marcel Goverde, *MGP Consulting*

- Regulatory Expectations
- Microbiological Specifications
- Testing Methods

### Development and Validation of a Cloud-based System for Automated Text Verification

Dr Carsten Börger, *Valicare*

Frank Hessler, *Schlafender Hase*

- User requirements for automated text verification for leaflets and graphical artworks
- Good documentation in software development
- Comparison of internal software validation for release versus software validation of a COTS-software
- Delimitation of duties in cloud-based system

### Distribution Testing: How to make sure, the Product makes it to the Destination

Dr Jan Oberländer, *GfPS*

- The significance of distribution testing and commonly applied standards
- Potential hazards on the transport field
- How to interpret the test results to optimize the packaging
- Improving the protecting function of the secondary packaging
- Subsequent testing on the primary packaging

## 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.

### 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

### Live Demos

#### Merck

- Annex 1's "Specific Risks Associated with Single-Use Systems"

#### Cytiva

- Point-of-use leak testing of single-use systems

### 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.

## MODERATOR

Frank Studt, *gempex*

### 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

Stephanie Ziesche, *ABX advanced biochemical compounds*

Dr Emad Albarouki, *Particle Measuring Systems*

- 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

### GMP compliant Environmental Monitoring

Dr Anne-Grit Klees, *Merck*

## OBJECTIVES

This is why you will benefit from attending this conference:

- Case studies from various pharmaceutical companies deal with the implementation, qualification and operation of Isolators, RABS systems and Robots.
- You will discuss the current state of the art and new technological developments in Barrier Systems and Pharmaceutical Robotics Technology.
- You will get to know first-hand the new EU-GMP Annex 1 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 stricter 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. Another consequence of the separation of operator and production process is the increased introduction of Robot Technology in the aseptic environment.

### Isolator / RABS: What is really new in Annex 1

Dr Florian Witte, *Boehringer Ingelheim Pharma*

- Classification by the authorities and in the current Annex 1
- What is suitable for whom?
- Advantages and disadvantages of isolators and RABS
- What is new about the classic cleanroom?

### Tackling Annex 1 Requirements by Robotics: On the Way to Zero Human Interaction in Lyo Vial Filling

Dr Arne Schröder, *Vetter Pharma-Fertigung*

- Cleanroom layout and processes for zero human interaction in lyo vial filling
- Replacement of manual processes by robots
- Challenges of implementing robots
- Lessons learned during the first years of commercial use

### Robotics and Automation – The Enabler for a higher Quality and Annex 1 CCS Compliance

Robert Kibele, *groninger & co*

- Current Annex 1 requirements and the reduction or elimination of human intervention within the ISO 5 environment
- How the usage of automation and robotics can support CCS
- Applying robotics in the pharmaceutical environment based on executed applications within aseptic environments
- Details about how to completely remove an operator from the aseptic environment

### Aseptic Process Simulation in a Robotic Filling Line

Dennis Dürr, *Roche Diagnostics*

- Short introduction/Oversight into APS and Robotic filling line
- Aseptic process simulations in robotic vs. conventional lines
- Thoughts and Rationales for APS in robotic filling line
- Insights into APS-concept for a robotic filling line

### Pre-Validation Steps of a fully gloveless Aseptic Isolator – A Case Study at the German CDMO PSM

Bianca Bohrer, *PSM*

- How to execute an APS for gloveless filling lines
- Challenges to overcome regarding the new Annex 1
- Is monitoring necessary in closed systems?
- Lessons learned in discussions with authorities

### Barrier Systems – Current GMP Requirements

Dr Daniel Müller, *Local GMP Authority of Baden-Württemberg, Germany*

- Regulatory overview: most important guidelines for barriers/isolators
- Revised Annex 1 section "barrier technologies" - changes and current requirements
- Annex 1 – fit for future now?

This conference will focus on current questions of barrier systems and robotics 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.

## TARGET AUDIENCE

This event is directed at decision-makers from pharmaceutical production, automation, 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 and robotics.

## MODERATORS

Didier Meyer, *DMCompliance*
Dr Florian Witte, *Boehringer Ingelheim Pharma*

### Case Study on Management of indirect Products Contact Parts in an Isolator

Antoine Toussaint, *GlaxoSmithKline Vaccines*

- Definition of indirect product contact part
- Regulation's requirement
- Example of implementation along the all lifecycle of indirect product contact parts

### Meeting EU GMP Annex 1 Requirements: Sterilization of indirect Product Contact Parts in Filling Lines using Sterilization Container

Dr Annika Bernsdorf, *GlaxoSmithKline Biologicals*

- Overview of the design of the current filling isolators at a GSK Vaccines manufacturing site and the challenges linked to traditional sterilization methods for parts indirectly in contact with the product
- Explanation of the features and benefits of sterilization containers as a compliant solution
- Customization of the containers to accommodate larger parts, such as the stopper bowl and stopper hopper
- Development of an improved line setup with enhanced contamination control

### Upgrade of $H_2O_2$ Dcontamination System for Production of RABS Vial Filling Line

Pasquale Cataldo, *Roche Diagnostics*
Kenan Kanmaz, *Optima pharma containment*

- Current process, why this upgrade – Annex 1
- Project challenge – timeline & installation vs. production
- Production shutdown and realization
- Risk and other key tasks of upgrading
- Results of project, cycles development and benefits
- Key features and advanced technologies of DECOpulse® – effective $H_2O_2$ Bio-decontamination system

### Case Study Janssen: Flexible Fill & Finish Equipment for Multi-Product Manufacturing Processes

Dr Göran Crucius, *Cilag / Janssen*
Patrick Wieland, *Bausch+Ströbel*

- Flexible multi-product fill and finish lines in pharmaceutical manufacturing offer several benefits that can help pharmaceutical companies improve their efficiency, flexibility and overall productivity
- Case Study of Janssens flexible pharma production to meet varying market demands and maintain product quality

### Modern Sterile Test Isolators – Safe, Compliant, Efficient, Versatile

Katharina Schlereth, *Labor LS*
Harald Kiesel, *Skan*

- Components of a modern Sterile Test Isolator
- Safe for operator and process
- Compliant during all aspects of use
- Efficient by adaptable to required processes
- Versatile in handling options

### Case Study: E-Beam – A validated Transfer Method for RTU into Grade A in Compliance with Annex 1

Anette Mörbel-Witte, *Sanofi-Aventis Deutschland*
Manfred Holzer, *Skan*

- E-beam used as transfer technology related to Annex 1
- Options for transfer of RTU
  - Emitter Technology
  - Properties of E-beam
- Validation
- History & Outlook
- Case study Sanofi Multi-Fill line

## OBJECTIVES

This conference will present state-of-the-art examples of cleanrooms, cleanroom technology and entire facilities. Requirements by the revised Annex 1 are thereby highlighted.

## BACKGROUND

Knowing the regulatory requirements on rooms and HVAC systems is an absolute prerequisite for all further steps like design, qualification and operation of clean rooms.

It is therefore essential to be aware of all restrictions and relations between material and personnel flows before starting with the building of clean rooms for pharmaceutical manufacturing. This is the starting point for the zone concepts and the required airlocks.

Depending on the product or project requirements, other points must also be considered, such as the filter technology, the design of the HVAC system and possibly tightness tests.

### Current Zoning Concepts for special Requirements

Andreas Nuhn, *D&B Pharmadesign*

- Zoning according to the new Annex 1
- Zone concepts for non-sterile dosage forms
- Special zone concepts and examples for
  - Cytological products
  - Radiopharmaceuticals
  - Biological products BSL 3

### Case Study Stulln Pharma - Design of a new Facility for Sterile Production

Nikolaus Ferstl, *Facility Engineering Services*

- General site master plan
- Production layout
- Facility and supply concept
- HVAC & zone concept
- Cleanroom walls, ceiling & floor

### New Cleanroom / Barrier System Requirements from Annex 1

Dr Jean Denis Mallet, *Former head of the French Inspection Department AFSSAPS, Pharmaplan*

- Premises
  - Is the traditional escalation D/C/B/A modified in Annex 1?
  - What is a 'new' airlock? What is a 'modern' air pressure cascade? What about continuous monitoring?
  - How to demonstrate that the aeraulic patterns are really those expected?
  - In which extent a barrier system can be considered as a premise?
- Equipment
  - Can we easily change the room design from an isolator system to a RABS system?
  - Is it interesting to combine RABS and isolators for the same filling line?
  - What is the best configuration for an aseptic vial capsuling machine?
- Personnel
  - How should we be qualified to enter in cleanrooms? D/C ... B/A?

### Implementation of the new Requirements of EU GMP Annex 1 from Boehringer Ingelheim's Perspective

Dr Lars Kreye, *Boehringer Ingelheim Pharma*

### Modern Cleanroom Garment Systems

Carsten Moschner, CMC3

### Green GMP in Cleanrooms – Contradiction or Opportunity

Dr Johannes Krämer, *CSL Behring*

- Compatibility of GMP and Sustainability?
- Approaches to sustainability in existing cleanrooms
  - Cleanroom operation/design/equipment
  - Plant and process operation
  - Maintenance/calibration
- Holistic approaches for new planning
  - Energy efficiency by process design
  - Thermal optimisation
  - Sustainable refrigeration
  - Minimising water consumption

The clean room itself consists of floor, wall and ceiling systems suitable for the intended use. Now, which systems are suitable for which clean zones or processes? How can an isolator be integrated in the concept? And what is the impact of the revised Annex 1 on clean rooms and HVAC systems?

## TARGET AUDIENCE

This conference is directed at specialists in pharmaceutical engineering departments and production, involved in the planning, qualification or operation of pharmaceutical manufacturing environments. Engineering companies and GMP-planners are also the target group of this conference.

## MODERATOR

Andreas Nuhn, *D&B Pharmadesign*

### HVAC-System Design for a High Potent Facility

Nikolaus Ferstl, *Facility Engineering Services*

- Cleanroom Classification & Pressure Zones
- HVAC Zoning and Segregation
- HVAC Supply Concepts
- Design Parameters
- Filtration Systems
- Tightness and tightness testing
- Examples, practical solutions

### Setup of a Contamination Control Strategy Using the HACCP Methodology

Ruben van der Galiën, *GE HealthCare*

- Application of the Hazard Analysis Critical Control Point (HACCP) methodology to monitor all Critical Control Points (CCPs) related to various sources of contamination
- Description of the way how to set up a CCS within a pharmaceutical sterile and aseptic manufacturing facility applying the HACCP methodology
- Use of the HACCP methodology enables a company to include proactive data within the CCS, making use of all identified sources of contamination, associated hazards, and/or control measures and CCPs
- The constructed CCS allows the manufacturer to identify whether all included sources of contamination are under control and, if not, which mitigatory actions need to be performed

### Airflow Visualization within the critical Zone of Cleanrooms and Barrier Systems

Luigi Scaffidi, *Boehringer Ingelheim Pharma*

- Regulatory requirements
- Prerequisites, techniques, operating states, relevant process steps, life cycle
- Selection of tracer particles (What's the deal with neutral buoyancy?)
- Case studies

### Cleanroom Performance Testing According ISO 14644

André Lourenço, *NNE*

- Introduction to Cleanroom Testing
- Strategy for Cleanroom Testing
- Practical Examples

### Case Study IPA Fraunhofer: Horizontal vs. vertical unidirectional Airflow Directions

Dr Markus Keller, *IPA Fraunhofer*

- New GMP Annex 1: first air principle
- ISO 14644-1: Examples from Space, MedTec, semiconductor industries
- Visualization setup regarding airflow studies for open vials
- Particle fallout risk assessment using silicon wafers as witness samples: Case scenarios:
  - Displacement pipetting robot with vertical airflow
  - Isolator with horizontal airflow

### Assessment of microbial Contamination in a sterile Production Environment

Doris Laçej, *Profarma*

In practice, environmental monitoring has shown that even a validated cleaning method using certified agents can lead to the presence of atypical microorganisms that exceed GMP limits.

- Challenges in the root cause analysis
- Integration of new disinfection methods
- Semi-automatic-disinfecting systems to eliminate *Aspergillus Niger* in grade A and C clean rooms

## OBJECTIVES

Reasons to attend this conference:

- You will get an overview of current digitalisation and artificial intelligence in the pharmaceutical industry.
- You will learn how efficiency and quality can be improved through the implementation of digitalisation.
- In various case studies of pharmaceutical companies, projects from practice are presented.

## BACKGROUND

New forms of digitalisation are finding their way more and more into the pharmaceutical industry. If the automation stage is already well advanced, topics such as AI, IOT and Industry 4.0 are waiting in the wings. Artificial Intelligence has arrived in the general public since Chat GPT and Bard but has also found its way into the pharmaceutical industry.

### An Overview on AI/ML in GxP Environments

Stefan Münch, *Körber Pharma Consulting*
Yves Samson, *Kereon*

- Basics of AI/ML
- AI/ML along the pharmaceutical value chain
- Promising use cases in pharma manufacturing
- Regulatory challenges of AI/ML in GxP
- Risks and Controls of AI/ML in GxP

### Regulatory Requirements and Inspector's View on Artificial Intelligence

Ib Alstrup, *Danish Medicines Agency, DMA*

### Use of AI in daily Deviation and CAPA Management

Dr Sven Alexander Moritz, *Sanofi-Aventis Deutschland*

- Use of AI to discover early signals in deviation trending
- Shorten investigation time
- Improve CAPA definition and implementation based on real life data

### Validation of AI/ML in the GxP Environment

Dr Ulrich Köllisch, *GxP-CC*

- Regulatory overview: What are the new guidelines, best industry practices and discussion papers on AI/ML validation (EMA, FDA)
- Prerequisites for AI/ML validation (Data Governance) and the AI/ML model Lifecycle
- Two case studies: High Level Risk Assessment for NLP implementation in the QMS and for visual inspection; Application of ICHQ9 (R1) with a patient-centric mindset
- Conclusion and Outlook: An industry overview of the current status and what is to be expected next

### When Data runs wild – Data Integrity as a Control Tool for AI

Galit Lisaey, *Gal.IT Data Integrity Consulting*

- The Importance of Data Integrity in Decision-Making
- Challenges: Transition to Automated Systems
- Data Integrity as an Organizational Interest
- Risks and Reliability in AI-Based System
- Immediate Solutions: Regulatory Tools and Methodologies

### Simplified Extractables and Leachables Assessment using prior Knowledge and IT Solutions

Dr Armin Hauk, *Sartorius Stedim Biotech*

- Prediction of extractables profiles for SU devices of different sizes and complex assemblies
- Calculation of exposure data, with a subsequent automated safety-assessment; including a discussion of deviations and propagation of deviations
- Equivalency study of extractables profiles of a SU assembly before and after a component change, including the evaluation of the impact on the safety assessment
- Using the system to extrapolate extractables data to USP <665> conditions for a safety assessment of a large volume injectable drug product


Therefore, the track will primarily be dedicated to Artificial Intelligence and present and discuss initial experience from established projects. The focus will be on GxP-relevant aspects from the perspective of the pharmaceutical industry and the regulatory authorities.

## TARGET AUDIENCE

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with digitalisation and AI projects. It particularly addresses the departments IT, Production, Quality assurance and Engineering / Technology.

## MODERATORS

Stefan Münch, *Körber Pharma Consulting*
Yves Samson, *Kereon*

### Applying Industry 4.0 – What are the Use Cases and how can they be successfully implemented

Dr Andreas Aemissegger , *Bachem*
Yvonne Duckworth, *CRB*

- The pharma industry is ready to move into the digital age and hungry for 4.0 advancements, but decision-makers are still unsure where and how to apply these technologies
- The speakers examine Pharma's use of Industry 4.0 from three angles: the owner, the service provider, and the governance
- Get an overview and examples of Industry 4.0 concepts along typical manufacturing processes within BACHEM AG
- Learn how the AEC industry is incorporating 4.0 into pharma facilities

### How the Digital Transformation could really improve Inspections & Audits Effectiveness and Efficiency

Dr Jean-Denis Mallet, *Former head of the French Inspection Department AFSSAPS, Pharmaplan*

- What e-technologies could add to the desired transparency of the inspection / audit process
- How confidence can be built through the e-technological approach
- Is 'AI' a Dr Jekyll approach or a Mr Hyde too?
- Conclusion: how to help 'AI' in the inspection / audit process

### Quality Contracts in the Era of Digitalisation and AI

Ioannis Tsiagkas, *Pharmathen*

- Digitalisation and AI can be utilized within pharmaceutical quality contracts to improve efficiency, accuracy, and compliance
- Document Management: AI-powered document management systems
- Supplier Quality Management: AI can assist in evaluating and monitoring the quality performance of suppliers involved in pharmaceutical manufacturing
- Compliance Monitoring: AI systems can detect deviations from contractual obligations and regulatory standards, providing real-time alerts and facilitating corrective actions
- Real-time Quality Monitoring: AI-powered monitoring systems can continuously collect and analyze data from various sources

### Bridging Innovation and Compliance: Open-Sourcing Data Computation Platform (DCP) for GxP-Compliant Pharma 4.0 Advancements

Dr Tobias Ladner, *Roche Diagnostics*

- Introducing Data Computation Platform (DCP): Enabling GxP-Compliant Advancements and Supporting Tools in One Platform
- Validation: Ensuring GxP Compliance and Reliability of the Data Computation Platform (DCP)
- Use Case: Leveraging DCP for GxP-Compliant Multivariate Data Analytics Process Monitoring
- Journey Towards Open-Sourcing: Overcoming Challenges and Fostering Collective Progress

### Enabling ML Applications by a "Data Expert Team"

Dr Jörg Stüben, *Boehringer Ingelheim International*
Martin Heitmann, *d-fine*

- Relevance of data in ML enabled applications
  - The Subject Matter Expert's view: Searching for the right use case
  - The Data Scientist's view: Searching for the right method
  - Reaching the common goal: The „Data Expert Team" featuring insights from real world examples

### Panel/Plenary Discussion

## OBJECTIVES

In this conference you will learn which requirements for pre-fillable syringes are defined by the regulations. You get to know all aspects of the manufacture of pre-fillable syringes that influence the filling process and the quality of the final product. In addition, practice-oriented case studies will guide you through the relevant production processes, simulations and controls for pre-filled syringes.

## BACKGROUND

Currently there is a growing demand in the development of pre-fillable syringes (e.g. ready-to-fill, ready-to-use, sterile clean filling) for several enhanced Biotech applications (i.e. for the final product, the Pre-filled Syringe). However, new GMP requirements, also for the sterile packaging material (e.g. regarding validation of the sterilization procedure for the syringe), apply with the revised **EU GMP Annex 1 entitled "Manufacture of Sterile Medicinal Products"**.

This event will therefore deal with the current discussions and trends in the manufacture of pre-filled syringes:

- GMP requirements for pre-fillable syringes / devices
- PFS Design & Safety Systems
- Alternatives to glass
- GMP Requirements for personnel, cleanrooms, equipment & facilities
- Processing of pre-filled syringes
- Auto-injector Assembling

### Regulatory Overview, Annex 1 Impact and Inspection experience

Dr Daniel Müller, *Local GMP Authority of Baden-Württemberg, Germany*

- Regulatory framework (EU), impact for pre-filled syringes
- Impact of new Annex 1
- Inspection experience

### Contamination Control Strategy

Marsha Steed, *Steed MicroBio*

Practical experiences

- CCS – a new Annex 1 requirement
- Case Study: CCS implementation
- Risk based approach for control point identification

### Medical Device Regulations - Understanding the Impacts and ensuring Compliance for Syringe-based Combination Products

Christa Jansen-Otten, *West*

- Navigating the EU MDR Regulations requirements
- Advantages of platforming on prefillable syringes
- Case example of technology being applied by the market for platform applications
- Needs of suppliers for supportive documentation

### PFS made from Glass or Polymer

Katharina Golly, *Novartis*

- Materials
- Manufacturing
- Sterilization methods
- Design
- Pros and Cons

### PFS and Needle Safety Systems

Katharina Golly, *Novartis*

Jinesh Sadalge, *Novartis*

- Regulatory Requirements
- Active vs. Passive Systems
- Design Considerations
- Examples

### Validation of a Steam Sterilization Process for a Pre-Filled Syringe

Maria Luisa Bernuzzi, *MesaLabs*

- Challenges in steam sterilization of a PFS and its biological validation
- How to manage a heat sensitive load
- Bioburden/biological indicators approach, D value determination and the correct choice of biological indicators
- Validating the specific cycle

- Contamination Control Strategy
- Observations during GMP inspections

The presentations will be provided in a practice-oriented way from the different viewpoints of authorities, suppliers of packaging materials / devices / services (including sterilization activities), and the pharmaceutical industry.

## TARGET AUDIENCE

This event is designed for employees working in the pharmaceutical industry (including drug device combination products), for suppliers of packaging materials & devices and to all who have to deal with the manufacture, control and release of prefilled syringes. They key areas are

- Sterile Production
- Packaging material / Device development
- Manufacturing / Processing / Assembling
- Quality Control
- Quality Assurance

## MODERATOR

Dr Wenzel Novak, *Gerresheimer Bünde*

### Container Closure Integrity

Jean-François Decoster, *UCB*

- Requirements for CCIT
- Method development and validation

### Process Simulation / Media Fill

Dr Helen Sauter, *Vetter Pharma-Fertigung*

- Media Fill Design
- Worst-case parameters & requirements
- Validation of processes with Media Fills
- Trends with regards to Media Fills

### Visual Inspection

Jean-François Decoster, *UCB*

- Requirements
- Method development and validation
- AQL testing
- Automated vs. semi-automated vs. manual inspection

### Automated Visual Inspection: Process and Transfer

Dr Max Scheible, *Vetter Pharma-Fertigung*

- Automated Visual Inspection (AVI) as an alternative to MVI
- State-of-the-art technologies for a robust and reproducible process
- Qualification & Transfer

### Endotoxin Detection in Pre-Filled Syringes: Challenges during Method Development and Validation

Dr Bernhard Illes, *Microcoat Biotechnologie*

- Introduction to Endotoxin testing and endotoxin masking (Low Endotoxin Recovery (LER))
- General approach for development and validation of endotoxin detection methods
- Considerations and challenges for method development and validation for PFS
- Case studies for method development and validation for GMP release testing

Image: GEA

## OBJECTIVES

Take advantage of the opportunity to focus on **freeze drying technologies and processes** and get a first-hand demonstration of solutions for diverse requirements. Further, you will learn how the freeze drying output is affected by different equipment, parameter changes, solvents, etc.

## BACKGROUND

Lyophilization (or freeze drying) is one of the most exciting technologies in the pharmaceutical industry, although it is a very old process for the preservation of unstable materials. Trends are growing towards using non-aqueous systems.

Additionally, Process Analytical Technology (PAT) / RTRT (Real Time Release Testing, Annex 17 of the EU GMP Guide) systems for in-line process monitoring are used to control and determine critical processing parameters. PAT plays also an important role in continuous lyophilization processes. According to ICH´s new guideline Q13 "*continuous manufacturing (CM) has potential for improving the efficiency, agility, and flexibility of drug substance and drug product manufacturing*". Regulatory agencies have seen more companies engaged in the development and implementation of CM in recent years than in the past.
Modern QbD (Quality by Design) development following ICH Q8, Q9 and Q10 is based on the objective to design a lyophilization cycle applying a systematic and scientific approach instead of trial

## Regulatory Overview, Annex 1 Impact and Inspection Experience

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

- Regulatory framework (EU), impact for Lyo-Products
- Impact of new Annex 1
- Inspection experience

## Process Validation of Lyophilized Products and ongoing Lifecycle Verification

Dr Andrea Weiland-Waibel, *ExplicatPharma*

- Critical quality attributes (CQAs) and critical process parameters (CPPs):
  - Assessment of CPPs through robustness testing to establish the process boundaries as the basis for the transfer from lab to commercial scale
- Freeze drying scale-up and validation:
  - Process qualification/validation in lyophilization strategies in relation to FDA/EMA modern process validation guidelines
- Process control strategies:
  - Hot and cold spot determination to allow for process control by using a product temperature PAT device

## Lyophilized Plasma Products – Experience and Technical Challenges in Refrigeration

Frank Heck, *CSL Behring*

The operator's point of view:

- Freeze technology through the ages
- Freeze drying, but please climate friendly
- Plate cooling and the requirements for technical components in the product environment
- Methodologies for condition-based technical monitoring
- Outlook

## Atmospheric Spray Freeze Drying

Prof Alf Lamprecht, *University of Bonn*

- Process understanding, monitoring & control
- Design of continuous lyophilization

## New Automatic Format Change System for the Transportation of Freeze-Drying Vials

Xavier Gómez, *Telstar*

- A new solution to preserve the integrity of the product and operator's safety during format changeover
- How to simplify logistics in pharmaceutical plants (cleaning, sterilization, storage area, etc.)
- Investment vs operational costs

## Improving the Sustainability of Pharmaceutical Freeze Drying

Dr Benjamin Ledermann, *GEA*

Thomas Beutler, *GEA*

- Natural refrigerants
- Microwave-assisted freeze drying
- Atmospheric spray freeze drying
- Drying time reduction
- GWP reduction

Image: GEA

and error. Sufficient process understanding is essential to achieve a robust production process and efficient handling of post-approval changes (life cycle management according to ICH Q12) of a freeze-drying process.
There is an increasing trend in aseptically produced lyophilized products, including peptides and proteins. Owing to the nature of these biological products, the lyo-cycle is more complicated and, in most cases, even longer than for other medicinal products.
The utility of lyophilization goes far beyond the vial. Principles of low temperature, low pressure can be applied to stabilize substances ranging from high potent APIs, novel medical devices, biologics and nanomaterials, freeze drying offers multiple opportunities.

## TARGET AUDIENCE

This conference addresses specialists and executives working in the fields of pharmaceutical manufacture, research and development and quality control, as well as engineers, project/facility engineers, especially those involved in the implementation of new monitoring methods for controlled nucleation, risk-based scale-up models and process technology for freeze drying processes. The conference is also of interest for participants working in the areas of container development and manufacturing process/packaging.

## MODERATOR

Dr Ingrid Walther, *Pharma Consulting Walther*

### Vials and Stoppers for Lyophilization

Francis Carroll, *West*

- Primary packaging aspects for lyophilization
- Considerations for lyo stoppers
- Considerations for lyo vials
- Volatile Extractables
- EU GMP Annex I

### Container Closure Integrity

Matthias Schaar, *Novartis*

- Applicable CCIT and Process Analytical Technologies via non-destructive methodologies
- Examples

### Aseptic Process Simulation (Media Fill)

Heide Nagel, *Novartis Pharma Stein*

- Media Fill Design
- Worst-case parameters for Media Fills
- Validation of lyophilization processes with Media Fills
- Requirements for Media Fills
- Trends with regards to Media Fills

### Annex 1 Upgrade of Aseptic Filling and Lyophilization of Parenterals in RABS

Dr Tino Galgon, *Lyocontract*

- GAP analysis in relation to the new Annex 1
- Risk-based determination of monitoring points for the B area
- Risk-based upgrade of monitoring in the aseptic core zone (RABS)
- Implementation of a new stopper sterilization and drying system
- Integration of a glove lifecycle including testing, cleaning and sterilization

### Aseptic Lyophilization with the Help of Protective Membrane Bags

Rolf Lenhardt, *Teclen*

- Annex 1 requirements for aseptic lyophilization processes
- Lyophilization protection with membrane technology for vials
- Sterile bagging unit for small sterile batches with open RABS or Isolator
- Are pilot freeze dryer without CIP/SIP suitable for aseptic processing in combination with sterile bagging unit

## OBJECTIVES

This conference track is aimed at all those who develop and manufacture cells, tissues, cell- and tissue-based products and ATMPs. The conference will address manufacturing challenges, e.g. GMP regulations, but also quality control issues, appropriate ways to maintain, assure and control the expected quality. Experienced speakers from the field of ATMP will explain the current requirements and report on their experiences during inspections and the implementation in the company.

## BACKGROUND

Modern systems of regenerative medicines, such as cells and tissues or ATMPs (gene therapeutics, somatic cell-based products and tissue-based products) represent an innovative group of drugs that is becoming increasingly important. With the entry into force several regulatory guidelines e.g. of the European Directive EC 1394/2007 for ATMPs, such products were classified as medicinal products and must therefore comply as such with the EU requirements for medicinal products. Although the biopharmaceutical industry has considerably intensified its activities in this field, many of these products are developed and manufactured at universities, hospitals and in small and medium-sized enterprises. These university or medical roots lead to special challenges for the respective institutions as well as for the regulatory authorities in fulfilling the compliance requirements for quality, safety and GMP aspects and approval. This is also forced by frequently given

### CMC Strategies for successful ATMP Commercialization

Alicja Fiedorowicz, *Dark Horse Consulting*

- Regulatory requirements and guidelines around ATMP's
- Risk management to ensure product safety and efficacy
- Scalable manufacturing processes
- Phase-appropriate analytical strategy

### Challenges in the Bench-to-Bedside Translation of Gene and Cell Therapeutics (GCT)

Prof Dr Sven Stegemann, *DWI – Leibniz-Institut für Interaktive Materialien e.V.*

- GCTs continue to emerge into personalized first line treatments especially in oncology and immunology
- Major challenges in clinical and commercial manufacturing remain to be solved
- Multidisciplinary collaboration will be crucial to assure the bench-to-bedside translation of innovative GCTs

### Decentralised Manufacturing for T-Cell Therapies

Dr Ursula Busse, *Tigen*

- Difficulties with centralized production
- Development of decentralised manufacturing for clinical and commercial supply
- Regulatory hurdles with decentralised manufacturing and how to overcome them

### Digital Evolution Strategies in Manufacturing, Science and Technology (MSAT)

Dr Veronika Nindl, *VTU Engineering*

A focus on:

- Biopharma Use Cases applying Process Analytical Technology (PAT)
- AI – based Data Mining for Smart Reporting
- Process Manufacturing Simulation & Scheduling

### Design Considerations for allogeneic Cell Therapies

Erik Steffensen, *Spot-on Pharma Consulting*

- How does a typical allogeneic manufacturing process look?
- What is critical to control during manufacturing of allogenic cell therapies?
- Considerations regarding upscaling and process transfer

### Challenges in allogeneic CAR-T Manufacturing using Viral Vectors and LNPs

Dr Juliane Heilig, *CMT Cellex Manufacturing Transports and Logistics*

- Comparison of autologous & allogeneic concept
- Viral vector transduction & LNP knock out rates
- Challenges in manufacturing and product characterization
- Storage of off the shelf products

manufacturing conditions, e.g. the open manipulation of cells and tissues, which are necessary for obtaining such products on a medical/surgical level or by the short shelf life of the obtained final product.
Challenges for small batch manufacturing, rapid testing and analysis and storage are only some of the challenges for such short shelf life products in terms of:

- Comparability with Compendial Methods
- Sensitivity and Robustness
- Suitability Testing and Validation
- Variability

## TARGET AUDIENCE

This conference is aimed at all persons who

- are involved in the extraction and manufacture of Cells, Tissues and ATMPs
- Responsible persons from quality assurance and control of Cells, Tissues and ATMPs
- are responsible for microbiological or analytical testing
- perform inspections or audits of ATMPs facilities
- deal with the authorisation

## MODERATORS

Dr Sabine Hauck, *Consultant*
Dr Ulrike Herbrand, *Charles River Laboratories*
*Chairs of ECA's ATMP Interest Group*

### Contamination Control Strategy (CCS) for ATMPs

Marsha Steed, *Steed MicroBio*

- Developing a CCS for ATMP manufacturing products & processes
- Microbial contamination risks and challenges for cell therapy products
- Human intervention risk relation to environmental monitoring program design
- Design of Aseptic Processing Simulation (APS) for cell therapy products

### Increase Risk Awareness: QRM for ATMPs

Dr Rainer Gnibl, *Government of Upper Bavaria, Germany*

- What does QRM mean?
- ICH Q9 Quality Risk Management (Overview)
- Boundaries & Limitations
- Examples from Guideline

### Viral Clearance ATMPs – What if the Product is a Virus?

Sandra Meier, *Charles River Laboratories*

- Challenges for viral clearance strategies during downstream manufacturing
- What are the possible problems and limitations?
- Potential virus safety strategies

### Effective Cell Culture Operations by accurate, non-invasive Determination of the critical Process Parameter pH in Roche's Drug Substance Network

Christian Klinger, *Roche*

- Opportunity statement: Limitations of current industry standard
- Proposed technical solution
- Manufacturability and Implementation in commercial manufacturing
- Results and value proposition

### Digital PCR for In-Process Control and Lot Release Testing of Gene Therapy Applications

Dr. Nicole Paland, *Minerva Biolabs*

- Determination of vector copy number (VCN) in CAR T-cells for cancer therapy by duplex dPCR
- Standard for accurate calculation of the VCN
- Determination of the titer of adeno-associated viral (AAV) vectors for In-process control and lot release testing
- Parallel detection of residual DNA by duplex dPCR

### Definition of CQA – What and When – and is PAT an Option?

Dr Sabine Hauck, *Consultant*
Dr Ulrike Herbrand, *Charles River Laboratories*
*Chairs of ECA's ATMP Interest Group*

- How to define CQAs for ATMPs?
- Best time to validate the assays
- The challenge of Bioassay development


## OBJECTIVES

The development and production of vaccines places high demands on the manufacturing pharmaceutical industry. The special requirements for handling and safety with living organisms require measures that go beyond the requirements of classical drug production. This conference track is aimed at all those who develop, manufacture, release vaccines and deal with regulatory issues. Experienced speakers from the field of vaccines will explain the current requirements, share their knowledge of new innovative achievements, report on their experiences and implementation in the company.

## BACKGROUND

"Vaccines are expected to be very safe" is one of the headlines in the presentation by CBER's Vaccine safety team. At the same time, many vaccines are being developed and new vaccines are still needed for diseases for which no vaccine is currently available, and production technologies need to be improved to produce high-quality and, above all, patient-safe product. This has led to the emergence of new technologies, approaches and guidelines. Through Corona, we have realized the importance of rapid development with subject matter expertise, as well as then manufacturing to the latest technology and requirements. Regulatory hur-

### Global Progress in Vaccine Development: Regulatory Considerations and Scientific Advances

Dr Mohamad Toutounji, *Molgenium*

- Evolution of Global Vaccine Regulations
- Challenges and Opportunities in Vaccine Access
- The Future of Vaccine Research and Development
- Implementing Vaccination Programs Worldwide

### Modern Vaccines – Perspective from the Regulatory Authority

Petra Falb, *AGES – Austrian Agency for Health and Food Safety*

- Changing regulatory Requirements for latest Technologies
- Regulatory Challenges – from conventional Antigens to Platforms
- User-related Technology Examples – RNA Vaccines / DNA Vaccines / Vector Vaccines

### Added Value by Advance Formulations for Vaccines

Dr Sabine Hauck, *ECA ATMP Interest Group*

- Selection of smart methods to assess stability during formulation development
- Advanced formulations - case studies
- Potential of stability prediction

### Low-Energy-Electron Irradiation – a potential Game Changer for the Development of Vaccines and Cell Therapies

Dr Andrea Traube, *KyooBe Tech*

- Explanation of low-energy electron irradiation (LEEI)
- Advantages compared to conventional methods
- Application in cell therapy and development of vaccines

### Resolving Facility Design Conflicts between Biocontainment & Good Manufacturing Practices for Vaccines Manufacture

Faye Litherland, *Fluor Limited*

- Facility location and layout
- Heating, Ventilation and Air Conditioning (HVAC)
- Construction methodology
- Utility supply

### The Search for efficacious and sustainable Alternatives to Triton™ X-100 in Therapeutics

James Humphrey, *Croda Pharma*

- An overview of the technical and regulatory challenges of finding suitable alternatives to Triton™ X-100
- Utilising structural characteristic and performance relationships to identify appropriate candidates to replace Triton™ X-100 in therapeutics
- Demonstrating the application performance of Triton™ X-100 alternatives for vaccine, biotherapeutic protein and gene therapy applications

dles, batch release, audits and purification are a few of the many issues that can complicate the supply and production of vaccines. The applications of vaccines seem limitless, but the implementation often fails. The typical questions often come up:

- What are the official requirements, that I have to implement?
- How can I implement this cost-effectively and as quickly as possible?
- How can I produce permanently with consistent quality and still improve my process?

## TARGET AUDIENCE

This conference is aimed at all persons who

- are involved in the development and manufacturing of vaccines
- Responsible persons from quality assurance and control
- are responsible for microbiological or analytical testing
- audit vaccine manufactures
- deal with authorisations

## MODERATOR

Clemens Mundo, *CONCEPT HEIDELBERG*

### Micro Array Patches for Vaccination

Sebastian Scherr, *LTS Lohmann Therapie-Systeme*

- What are Micro Array Patches (MAP)?
- Manufacturing of MAP
- MAP vaccine studies - preclinical and clinical results Batch Release of Vaccines

### Batch Release of Vaccines

Dr Alexander Bachmann, *Pharmaceutical Consultancy Dr Bachmann*

- Batch release of IMP vaccines
- Batch release of authorized vaccines

### Modern Vaccines – GMP Inspector's View

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

- Regulatory Guidelines
- Specific Aspects for modern Vaccines
- GMP-Inspections in Vaccine Production

### Considerations for Cleaning Lipid Nanoparticles

Cecilia Pierobon, *STERIS Life Sciences*

- Application and advantages of Lipid Nanoparticles (LNP)
- Hurdles with cleaning of LNP
- Case Study: General cleaning recommendation based on laboratory and field testing

### USP Approach to mRNA and Viral Vector Vaccines

Nikhil Rautela, *USP*

- mRNA and Viral Vector Draft Guideline updates
- Toolkit
- Other vaccine resources at USP

### mRNA as API and as Part of LNP Structure

Dr Natalia Markova, *Malvern Panalytical*

- Developability challenge with nucleic acid-based drugs
- Light-scattering and calorimetric techniques as fit-for-purpose analytics
- Informing on structure-function relationship

| Time | Non-Sterile Products | GMP – Green or Good Manufacturing Practice? | European Aseptic Conference | Trends in Barr Robo |
|---|---|---|---|---|
| Room | Studio 1.3 CD | Loge 1.1 | Forum 1.2 | Stud |
| 9:00 h<br>9:15 h<br>9:30 h | Manufacturing of Pandemic Vaccines – Manufacturing & Supply S<br>Dr Guido Di<br>Wallhäußer Innovati | | | |
| 9:45 h | Break | | | |
| 10:00 h<br>10:15 h | Live Demos<br>Ellab<br>boTec | | | |
| 10:30 h<br>10:45 h<br>11:00 h | Fully Automated and DoE-Based Development of an Oral Solid Dosage Form<br>*Dr Thomas Brinz, Syntegon* | Sustainability and GMP – Contradictive or supportive? How can Sustainability Aspects been built in GMP Requirements<br>*Dr Andrea Bauer, ABC&Q* | Compliance in Aseptic Production from a QP-Perspective<br>*Dr Rita Jacobs-Haage, Vetter Pharma-Fertigung* | Isolator / RABS: W Annex 1<br>*Dr Florian Witte, Boeh Pharma* |
| 11:15 h<br>11:30 h<br>11:45 h | Use and Implementation of SIX sigma and SPC (Statistical Process Control) Cp and CpK to improve our Routine Production Process throughout finding the Problems<br>*Pranvera Apostoli, Profarma* | Reading the EU-GMP Guide with green Glasses<br>*Dr Jean-Denis Mallet, PharmaPlan* | Live Demos<br>Bausch+Ströbel<br>Merck<br>Cytiva | Tackling Annex 1 R Robotics: On the W Interaction in Lyo V<br>*Dr Arne Schröder, Vett* |
| 12:00 h<br>12:15 h | Bre | | | |
| 12:30 h<br>12:45 h<br>13:00 h | Live Demos<br>MK Versuchsanlagen<br>Innerspace<br>MBV | | | |
| 13:15 h | Bre | | | |
| 13:30 h<br>13:45 h<br>14:00 h | EU-GMP Inspection: Inspector's hot Topics<br>*Dr Rainer Gnibl, Government of Upper Bavaria* | Does Sustainability stand only for green GMP?<br>*Ana Cláudia Pinho, Bial Portela Susana Lima, Bial Portela* | Industry asks – Annex 1 unfortunately does not answer! – What to do?<br>*Dr Ingrid Walther, Pharma Consulting Walther* | Robotics and Auto Enabler for a highe Annex 1 CCS Comp<br>*Robert Kibele, groning* |
| 14:15 h<br>14:30 h<br>14:45 h | Cleaning Validation in Pharmaceutical Manufacturing Industry<br>*Eni Bushi, Profarma* | Sustainable and Energy-Efficient Planning and Construction of a Laboratory and Production Facility<br>*Dr Johannes Reich, Microcoat Biotechnologie* | Aseptic Production in the Light of the new Annex 1<br>*Dr Frank Sielaff, Hessian State Office of Health and Care* | Aseptic Process Sir Robotic Filling Line<br>*Dennis Dürr, Roche Di* |
| 15:00 h<br>15:15 h<br>15:30 h | Break<br>Live Demos<br>ZETA<br>Friedrich Sailer<br>Particle Measuring Systems | | | |
| 15:45 h<br>16:00 h<br>16:15 h | Modern Approach for Identifying Sampling Points in the Non-Sterile Area (grid-line Approach)<br>*Dr Marcel Goverde, MGP Consulting* | Sustainability – HVAC Optimization Program at Merck Healthcare KGaA with significant Energy Savings<br>*Lenz Kunath, Merck Healthcare* | Advancing Aseptic Manufacturing: Insights and Best Practices from a Chief Quality Assurance Officer<br>*Dr Hiva Hossein Tehrani, CinnaGen* | Pre-Validation Ste gloveless Aseptic I Study at the Germa<br>*Bianca Bohrer, PSM* |
| 16:30 h<br>16:45 h | USP chapter <1115> – Industrial Implementation<br>*Dr Marcel Goverde, MGP Consulting* | How to reduce Carbon & Water Footprint in clean Utility Systems<br>*Alistair Wotherspoon, CRB* | Small Volume sterile Manufacturing – Challenges derived from new GMP Annex 1<br>*Marta Rodríguez-Vélez, Letipharma* | Barrier Systems – Requirements<br>*Dr Daniel Müller, Loca Baden-Württemberg* |
| 17:00 h | A Case of *Burkholderia cepacia* Complex in Non-Sterile Manufacturing; *Rashid Kihwelo, Kairuki* | | | |
| 17:15 h | | Sustainability in Pharma – how a Company can achieve $CO_2$ net zero Goal; *Henning Austermann, Siegfried Markus Burkert, Syntegon* | Discussion | Discussion |
| 17:30 h | Social Event | | | |

Content and times subject to change. For updates please see the info board at the registration desk or

| ier Systems & otics | Modern Cleanroom Technology | Digitalisation & Artificial Intelligence | GMP for Pre-Filled Syringes (PFS) | Time |
|---|---|---|---|---|
| io 1.1 | Forum 1.3 | Forum 1.1 | Studio 1.4 | Room |
| olutions Enabling the Delivery of Large Numbers of Vaccine Doses<br>ietrich, *CEPI* | | | | 9:00 h<br>9:15 h |
| ion Award Ceremony | | | | 9:30 h |
| | | Break | | 9:45 h |
| | | Live Demos<br>Ellab<br>boTec | | 10:00 h<br>10:15 h |
| hat is really new in<br>*hringer Ingelheim* | Current Zoning Concepts for special Requirements<br>*Andreas Nuhn, D&B Pharmadesign* | An overview on AI/ML in GxP Environments<br>*Stefan Münch, Körber Pharma Consulting*<br>*Yves Samson, Kereon* | Regulatory Overview, Annex 1 Impact and Inspection Experience<br>*Dr Daniel Müller, Local GMP Authority of Baden-Württemberg* | 10:30 h<br>10:45 h<br>11:00 h |
| equirements by<br>Way to Zero Human<br>Vial Filling<br>*ter Pharma-Fertigung* | Case Study Stulln Pharma – Design of a new Facility for Sterile Production<br>*Nikolaus Ferstl, Facility Engieering Services* | Regulatory Requirements and Inspector's View on Artificial Intelligence<br>*Ib Alstrup, Danish Medicines Agency* | Contamination Control Strategy<br>*Marsha Steed, Steed MicroBio* | 11:15 h<br>11:30 h<br>11:45 h |
| eak | | | | 12:00 h<br>12:15 h |
| | | Live Demos<br>MK Versuchsanlagen<br>Innerspace<br>MBV | | 12:30 h<br>12:45 h<br>13:00 h |
| eak | | | | 13:15 h |
| mation – The<br>r Quality and<br>bliance<br>*er & co* | New Cleanroom / Barrier System Requirements from Annex 1<br>*Dr Jean Denis Mallet, Former head of the French Inspection Department AFSSAPS, Pharmaplan* | Use of AI in daily Deviation and CAPA Management<br>*Dr Sven Alexander Moritz, Sanofi-Aventis Deutschland* | MDR – Understanding the Impact and ensuring Compliance for Syringe-based Combination Products<br>*Christa Jansen-Otten, West* | 13:30 h<br>13:45 h<br>14:00 h |
| mulation in a<br>e<br>*agnostics* | Implementation of the new Requirements of EU GMP Annex 1 from Boehringer Ingelheim's Perspective<br>*Dr Lars Kreye, Boehringer Ingelheim Pharma* | Validation of AI/ML in the GxP Environment<br>*Dr Ulrich Köllisch, GxP-CC* | PFS made from Glass or Polymer<br>*Katharina Golly, Novartis* | 14:15 h<br>14:30 h<br>14:45 h |
| | | Break<br>Live Demos<br>ZETA<br>Friedrich Sailer<br>Particle Measuring Systems | | 15:00 h<br>15:15 h<br>15:30 h |
| ps of a fully<br>solator – A Case<br>an CDMO PSM | Modern Cleanroom Garment Systems<br>*Carsten Moschner, CMC3* | When Data runs wild – Data Integrity as a Control Tool for AI<br>*Galit Lisaey, Gal.IT Data Integrity Consulting* | PFS and Needle Safety Systems<br>*Katharina Golly, Novartis*<br>*Jinesh Sadalge, Novartis* | 15:45 h<br>16:00 h<br>16:15 h |
| Current GMP<br>*l GMP Authority of* | Green GMP in Cleanrooms – Contradiction or Opportunity<br>*Dr Johannes Krämer, CSL Behring* | Simplified Extractables and Leachables Assessment using prior Knowledge and IT Solutions<br>*Dr Armin Hauk, Sartorius Stedim Biotech* | Validation of a Steam Sterilization Process for a Pre-Filled Syringe<br>*Maria Luisa Bernuzzi, MesaLabs* | 16:30 h<br>16:45 h<br>17:00 h |
| | Discussion | Discussion | Discussion | 17:15 h |
| | | Social Event | | 17:30 h |

join the PharmaCongress & PharmaTechnica WhatsApp channel by scanning the QR code in the app.

| Time | Lyophilization | ATMPs | Vaccines |
|---|---|---|---|
| Room | Studio 1.5 | Studio 1.2 | Studio 1.3 AB |
| 9:00 h<br>9:15 h<br>9:30 h | **Manufacturing of Pandemic Vaccines – Manufacturing & Supply Solutions Enabling the Delivery of Large Numbers of Vaccine Doses**<br>Dr Guido Dietrich, *CEPI*<br>**Wallhäußer Innovation Award Ceremony** | | |
| 9:45 h | Break | | |
| 10:00 h<br>10:15 h | **Live Demos**<br>Ellab<br>boTec | | |
| 10:30 h<br>10:45 h<br>11:00 h | Regulatory Overview, Annex 1 Impact and Inspection Experience<br>*Dr Frank Sielaff, Hessian State Office of Health and Care* | CMC Strategies for successful ATMP Commercialization<br>*Alicja Fiedorowicz, Dark Horse Consulting* | Global Progress in Vaccine Development: Regulatory Considerations and Scientific Advances<br>*Dr Mohamad Toutounji, Molgenium* |
| 11:15 h<br>11:30 h<br>11:45 h | Process Validation of Lyophilized Products and ongoing Lifecycle Verification<br>*Dr Andrea Weiland-Waibel, ExplicatPharma* | Challenges in the Bench-to-Bedside Translation of Gene and Cell Therapeutics (GCT)<br>*Prof Dr Sven Stegemann, Leibniz Jointlab „First-in-Translation“* | Modern Vaccines – Perspective from the Regulatory Authority<br>*Petra Falb, AGES - Austrian Agency for Health and Food Safety* |
| 12:00 h<br>12:15 h | Break | | |
| 12:30 h<br>12:45 h<br>13:00 h | **Live Demos**<br>MK Versuchsanlagen<br>Innerspace<br>MBV | | |
| 13:15 h | Break | | |
| 13:30 h<br>13:45 h<br>14:00 h | Lyophilized Plasma Products – Experience and Technical Challenges in Refrigeration<br>*Frank Heck, CSL Behring* | Decentralised Manufacturing for T-Cell Therapies<br>*Dr Ursula Busse, Tigen* | Added Value by Advanced Formulations for Vaccines<br>*Dr Sabine Hauck, ECA ATMP Interest Group* |
| 14:15 h<br>14:30 h<br>14:45 h | Atmospheric Spray Freeze Drying<br>*Prof Alf Lamprecht, University of Bonn* | Digital Evolution Strategies in Manufacturing, Science and Technology (MSAT)<br>*Dr Veronika Nindl, VTU Engineering* | Low-Energy-Electron Irradiation – a Potential Game Changer for the Development of Vaccines and Cell Therapies<br>*Dr Andrea Traube, Kyoobe Tech* |
| 15:00 h<br>15:15 h<br>15:30 h | Break<br>**Live Demos**<br>ZETA<br>Friedrich Sailer<br>Particle Measuring Systems | | |
| 15:45 h<br>16:00 h<br>16:15 h | New Automatic Format Change System for the Transportation of Freeze-Drying Vials<br>*Xavier Gómez, Telstar* | Design Considerations for allogeneic Cell Therapies<br>*Erik Steffensen, Spot-on Pharma Consulting* | Resolving Facility Design Conflicts between Biocontainment & Good Manufacturing Practices for Vaccines Manufacture<br>*Faye Litherland, Fluor Limited* |
| 16:30 h<br>16:45 h<br>17:00 h | Improving the Sustainability of Pharmaceutical Freeze Drying<br>*Dr Benjamin Ledermann, GEA*<br>*Thomas Beutler, GEA* | Challenges in allogeneic CAR-T Manufacturing using Viral Vectors and LNPs<br>*Dr Juliane Heilig, CMT* | The Search for efficacious and Sustainable Alternatives to Triton™ X-100 in Therapeutics<br>*James Humphrey, Croda Pharma* |
| 17:15 h | Discussion | Discussion | Discussion |
| 17:30 h | Social Event | | |

Content and times subject to change. For updates please see the info board at the registration desk or

| Packaging / Packaging Materials | European Aseptic Conference | Trends in Barrier Systems & Robotics | Time |
|---|---|---|---|
| Studio 1.3 CD | Forum 1.2 | Studio 1.1 | Room |
| Keynote by the Wallhäußer Innovation Award Winner | | | 9:00 h<br>9:15 h<br>9:30 h |
| Break<br>Live Demos<br>PHARMAPLAN<br>Emerson Automation Solutions<br>Yokogawa Deutschland | | | 9:45 h<br>10:00 h<br>10:15 h |
| Primary and Secondary Packaging of Drug Substances<br>*Jyotsna Agnihotry, Flavine Europe* | Single-Use Design for Small-Volume Filling<br>*Julia Mathy, Roche Diagnostics* | Case Study on Management of indirect Products Contact Parts in an Isolator<br>*Antoine Toussaint, GlaxoSmithKline Vaccines* | 10:30 h<br>10:45 h<br>11:00 h |
| Regulatory demands / Challenges in CCS of Injections<br>*Pirkko Lahti, Orion* | Container Closure Integrity Testing (CCIT) and Biologics – Some Case Studies<br>*Dr Constantin Hozsa, Siegfried* | Meeting EU GMP Annex 1 Requirements: Sterilization of indirect Product Contact Parts in Filling Lines using Sterilization Container<br>*Dr Annika Bernsdorf, GlaxoSmithKline Biologicals* | 11:15 h<br>11:30 h<br>11:45 h |
| Live Demos<br>REA Elektronik<br>IWT / Tecniplast<br>Quascenta Pte<br>Kneat Solutions | | | 12:00 h<br>12:15 h<br>12:30 h<br>12:45 h |
| Break | | | 13:00 h |
| Packaging Materials Challenges in Aseptic / Sterile Manufacturing<br>*Sergio Cuevas Luján, Boehringer Ingelheim* | Particle Life Cycle Concept<br>*Dr Philip Hörsch, Vetter Pharma-Fertigung* | Upgrade of $H_2O_2$ Decontamination System for Production oRABS Vial Filling Line<br>*Pasquale Cataldo, Roche Diagnostics*<br>*Kenan Kanmaz, Optima pharma containment* | 13:15 h<br>13:30 h<br>13:45 h |
| Microbiological Control of Packaging Materials<br>*Dr Marcel Goverde, MGP Consulting* | Implementation and Execution of an active microbial Air Monitoring System into a sterile, radiopharmaceutical Environment<br>*Stephanie Ziesche / Dr Emad Albarouki* | Case Study Janssen: Flexible Fill & Finish Equipment for Multi-Product Manufacturing Processes<br>*Dr Göran Crucius, Cilag / Janssen*<br>*Patrick Wieland, Bausch+Ströbel* | 14:00 h<br>14:15 h<br>14:30 h |
| Break | | | 14:45 h<br>15:00 h |
| Development and Validation of a Cloud-based System for Automated Text Verification<br>*Dr Carsten Börger, Valicare*<br>*Frank Hessler, Schlafender Hase* | Case Study: Critical Process Parameters for Filling of Sterile Products with BFS Technology<br>*Dr Martin Haerer, Rommelag CMO* | Modern Sterile Test Isolators – Safe, Compliant, Efficient, Versatile<br>*Katharina Schlereth, Labor LS*<br>*Harald Kiesel, Skan* | 15:15 h<br>15:30 h<br>15:45 h |
| Distribution Testing: How to make sure, the Product makes it to the Destination<br>*Dr Jan Oberländer, GfPS* | GMP compliant Environmental Monitoring<br>*Dr Anne-Grit Klees, Merck* | Case Study: E-Beam – A validated Transfer Method for RTU into Grade A in Compliance with Annex 1<br>*Anette Mörbel-Witte, Sanofi-Aventis Deutschland*<br>*Manfred Holzer, Skan* | 16:00 h<br>16:15 h<br>16:30 h |
| Discussion | Discussion | Discussion | 16:45 h<br>17:00 h |
| | | | 17:15 h<br>17:30 h |

join the PharmaCongress & PharmaTechnica WhatsApp channel by scanning the QR code in the app.

| Time | Modern Cleanroom Technology | Digitalisation & Artificial Intelligence | GMP for Pre-Filled Syringes (PFS) |
|---|---|---|---|
| Room | Forum 1.3 | Forum 1.1 | Studio 1.4 |
| 9:00 h<br>9:15 h<br>9:30 h | | | Keynote by the Wallhäußer |
| 9:45 h<br>10:00 h<br>10:15 h | Break<br>**Live Demos**<br>PHARMAPLAN<br>Emerson Automation Solutions<br>Yokogawa Deutschland | | |
| 10:30 h<br>10:45 h<br>11:00 h | HVAC-System Design for a High Potent Facility<br>*Nikolaus Ferstl, Facility Engieering Services* | Applying Industry 4.0 – What are the Use Cases and how can they be successfully implemented<br>*Dr Andreas Aemissegger, Bachem*<br>*Yvonne Duckworth, CRB* | Container Closure Integrity<br>*Jean-François Decoster, UCB* |
| 11:15 h<br>11:30 h<br>11:45 h | Setup of a Contamination Control Strategy Using the HACCP Methodology<br>*Ruben van der Galiën, GE HealthCare* | How the Digital Transformation could really improve Inspections & Audits Effectiveness and Efficiency<br>*Dr Jean Denis Mallet, Former head of the French Inspection Department AFSSAPS, Pharmaplan* | Process Simulation / Media Fill<br>*Dr Helen Sauter, Vetter Pharma-Fertigung* |
| 12:00 h<br>12:15 h<br>12:30 h<br>12:45 h | **Live Demos**<br>REA Elektronik<br>IWT / Tecniplast<br>Quascenta Pte<br>Kneat Solutions | | |
| 13:00 h | Break | | |
| 13:15 h<br>13:30 h<br>13:45 h | Airflow Visualization within the critical Zone of Cleanrooms and Barrier Systems<br>*Luigi Scaffidi, Boehringer Ingelheim Pharma* | Quality Contracts in the Era of Digitalisation and AI<br>*Ioannis Tsiagkas, Pharmathen* | Visual Inspection<br>*Jean-François Decoster, UCB* |
| 14:00 h<br>14:15 h<br>14:30 h | Cleanroom Performance Test According ISO 14644<br>*André Lourenço, NNE* | Bridging Innovation and Compliance: Open-Sourcing Data Computation Platform (DCP) for GxP-Compliant Pharma 4.0 Advancements<br>*Dr Tobias Ladner, Roche Diagnostics* | Automated Visual Inspection: Process and Transfer<br>*Dr Max Scheible, Vetter Pharma-Fertigung* |
| 14:45 h<br>15:00 h | Break | | |
| 15:15 h<br>15:30 h<br>15:45 h | Case Study IPA Fraunhofer: Horizontal vs. vertical unidirectional Airflow Directions<br>*Dr Markus Keller, IPA Fraunhofer* | Enabling ML Applications by a "Data Expert Team"<br>*Dr Jörg Stüben, Boehringer Ingelheim International*<br>*Martin Heitmann, d-fine* | Endotoxin Detection in Pre-Filled Syringes: Challenges during Method Development and Validation<br>*Dr Bernhard Illes, Microcoat Biotechnologie* |
| 16:00 h<br>16:15 h<br>16:30 h | Assessment of microbial Contamination in a sterile Production Environment<br>*Doris Laçej, Profarma* | Panel/Plenary Discussion | Discussion |
| 16:45 h | Discussion | Discussion | |
| 17:00 h | | | |

Content and times subject to change. For updates please see the info board at the registration desk or

| Lyophilization | ATMPs | Vaccines | Time |
|---|---|---|---|
| Studio 1.5 | Studio 1.2 | Studio 1.3 AB | Room |
| r Innovation Award Winner | | | 9:00 h<br>9:15 h<br>9:30 h |
| Break<br>**Live Demos**<br>PHARMAPLAN<br>Emerson Automation Solutions<br>Yokogawa Deutschland | | | 9:45 h<br>10:00 h<br>10:15 h |
| Vials and Stoppers for Lyophilization<br>*Francis Carroll, West* | Contamination Control Strategy (CCS) for ATMP<br>*Marsha Steed, Steed MicroBio* | Micro Array Patches for Vaccination<br>*Sebastian Scherr, LTS Lohmann Therapie-Systeme* | 10:30 h<br>10:45 h<br>11:00 h |
| Container Closure Integrity<br>*Matthias Schaar, Novartis* | Increase Risk Awareness: QRM for ATMPs<br>*Dr Rainer Gnibl, Government of Upper Bavaria* | Batch Release of Vaccines<br>*Dr Alexander Bachmann, Pharmaceutical Consultancy Dr Bachmann* | 11:15 h<br>11:30 h<br>11:45 h |
| **Live Demos**<br>REA Elektronik<br>IWT / Tecniplast<br>Quascenta Pte<br>Kneat Solutions | | | 12:00 h<br>12:15 h<br>12:30 h<br>12:45 h |
| Break | | | 13:00 h |
| Process Simulation / Media Fill<br>*Heide Nagel, Novartis Pharma Stein* | Viral Clearance ATMPs – What if the Product is a Virus?<br>*Sandra Meier, Charles River Laboratories* | Modern Vaccines - GMP Inspectors View<br>*Dr Frank Sielaff, Hessian State Office Of Health and Care* | 13:15 h<br>13:30 h<br>13:45 h |
| Annex 1 Upgrade of Aseptic Filling and Lyophilization of Parenterals in RABS<br>*Dr Tino Galgon, Lyocontract* | Effective Cell Culture Operations by accurate, non-invasive Determination of the critical Process Parameter pH in Roche's Drug Substance Network<br>*Christian Klinger, Roche* | Considerations for Cleaning Lipid Nanoparticles<br>*Cecilia Pierobon, STERIS Life Sciences* | 14:00 h<br>14:15 h<br>14:30 h |
| Break | | | 14:45 h<br>15:00 h |
| Aseptic Lyophilization with the Help of Protective Membrane Bags<br>*Rolf Lenhardt, Teclen* | Digital PCR for In-Process Control and Lot Release Testing of Gene Therapy Applications<br>*Dr Nicole Paland, Minerva Biolabs* | USP Approach to mRNA and Viral Vector Vaccines<br>*Nikhil Rautela, USP* | 15:15 h<br>15:30 h<br>15:45 h |
| Discussion | Definition of CQA – What and When – and is PAT an Option?<br>*Dr Sabine Hauck, Consultant*<br>*Dr Ulrike Herbrand, Charles River Laboratories*<br>*Chairs ECA ATMP Interest Group* | mRNA as API and as Part of LNP Structure<br>*Natalia Markova, Malvern Panalytical* | 16:00 h<br>16:15 h<br>16:30 h |
| | Discussion | Discussion | 16:45 h |
| | | | 17:00 h |

## 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. 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.

## Location

RheinMain CongressCenter (rmcc)
Friedrich-Ebert-Allee 1
65189 Wiesbaden
Phone: +49 (0) 611 1729-444
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|---|---|---|
| Non-Sterile Products | ☐ | n.a. |
| GMP – Green or Good Manufacturing Practice? | ☐ | n.a. |
| Packaging/Packaging Materials | n.a. | ☐ |
| European Aseptic Conference | ☐ | ☐ |
| Trends in Barrier Systems & Robotics | ☐ | ☐ |
| Modern Cleanroom Technology | ☐ | ☐ |
| Digitalisation & Artificial Intelligence | ☐ | ☐ |
| GMP for Pre-Filled Syringes (PFS) | ☐ | ☐ |
| Lyophilization | ☐ | ☐ |
| ATMPs | ☐ | ☐ |
| Vaccines | ☐ | ☐ |
| Participation in Social Event | ☐ | n.a. |
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