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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 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.

The GMP PharmaCongress Conference Tracks *click on the conference title to directly get to the resp. page*	19 March 2024	20 March 2024	Page
Non-Sterile Products – Challenges in Manufacturing & Quality	✓	n.a.	7
GMP – Green or Good Manufacturing Practice?	✓	n.a.	8
Packaging/Packaging Materials – Challenges & Solutions	n.a.	✓	9
European Aseptic Conference – Technology	✓	✓	10/11
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

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€ 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?
Axel H. Schroeder (Operations Director),
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European Aseptic Conference | Trends in Barrier Systems & Robotics | Digitalisation & Artificial Intelligence
Dr Andreas Mangel (Operations Director),
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Modern Cleanroom Technology
Dr Robert Eicher (Operations Director),
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Packaging/Packaging Materials – Challenges & Solutions | GMP for Pre-Filled Syringes (PFS) | Lyophilization – Modern Techniques & New Requirements
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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 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
The CEPI Project – 40 Countries – 1 Billion Euros for Vaccines

Dr Guido Dietrich, *CEPI*

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

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

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

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

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

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SPEAKERS

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

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

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

Alya Aldahash
SFDA – National Regulatory Authority, *Senior Pharmacist.*

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

Pranvera Apostoli
Profarma, *QA and RA Manager.*

Henning Austermann
Siegfried.

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

Dr Andrea Bauer

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

Maria Luisa Bernuzzi
MESA 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.*

Dr Thomas Brinz
Syntegon.

Markus Burkert
Syntegon.

Eni Bushi
Profarma, *Validation Manager.*

Francis Carroll
West, Ireland, *Technical Specialist.*

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

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

Dr Tony Cundell
Microbiological Consulting, LLC, *Principal Consultant.*

Yogesh K. Davé
Cypress Quality Consultancy Ltd, *Managing Director.*

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

Manuel André Deuringer
Lonza, *Associate Director Clean Utilities Engineering.*

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

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

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

Nikolaus Ferstl
University Hospital of Regensburg, *Technical Director.*

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

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

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

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

Thorsten Häfner
PSM, Schiffweiler, Germany, *VP Business Development.*

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

Dr Sabine Hauck
Leukocare AG, *EVP Corporate Development.*

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

Frank Heck
CSL Behring, Germany.

Irene Heiderich
Boehringer Ingelheim, *Internal Auditor.*

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

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

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

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

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

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

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

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

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

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

Daniela Jahn
Boehringer Ingelheim RCV, *Head of the Unit for process equipment qualification.*

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

Kenan Kanmaz
Metall+Plastic, Radolfzell, Germany, *Technical Sales Manager.*

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

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

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

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

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

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

Dr Lars Kreye
Boehringer Ingelheim Pharma GmbH & Co. KG, *Head of Regulatory Compliance.*

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

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

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

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

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

Dr Hadj Latreche
F. Hoffmann-La Roche AG, Basel, Switzerland, *Global Digital Strategy and Value Realization.*

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, *Environment Specialist.*

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

Faye Litherland
Blue Sky Process Engineering Ltd, *Subject Matter Expert - Drug Substance and Biocontainment at IPS - Integrated Project Services.*

André Lourenco
NNE, *HVAC & Cleanroom Specialist Engineer.*

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

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

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

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

Didier Meyer
DMCompliance, *Consultant.*

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

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

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

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

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

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

Julian Petersen
groninger & co., *Director of Business Development and Product Management.*

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

Ana Cláudia Pinho

Mahboobeh Rastegar
GfPS, Germany, *Expert in stability, performance as well as integrity testing.*

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

GMP-PHARMA CONGRESS

SPEAKERS

Dr Johannes Reich
Microcoat Biotechnologie.

Marta Rodríguez Vélez
Letipharma, Tres Cantos, Spain, *Quality Assurance.*

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

Dr Daniel Samson
Bachem AG, Bubendorf, Switzerland, *Head Olegonucleotides.*

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

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

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

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

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

Katharina Schlereth
Labor L+S, Bad Bocklet, Germany, *Division Head, Microbiological Testing of Sterile Products.*

Dr Arne Schröder
Vetter Pharma-Fertigung, Ravensburg, 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, Darmstadt, Germany, *GMP Inspector.*

Alexandra Stärk
Novartis, Switzerland, *Team Lead microbiological experts in the department of Manufacturing, Science & Technology.*

Marsha Steed
Resilience, *Head of Global Microbial Control & Sterility Assurance.*

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

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

Frank Studt
gempex, *Managing Director.*

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

Dr Mohamad Toutounji
Molgenium, *CEO & Founder.*

Dr Andrea Traube
KyooBe Tech GmbH, *CEO.*

Ioannis Tsiagkas
Pharmathen S.A., Pallini, Attica, Greece, *Technical/Quality Agreements Specialist.*

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

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

Olaf Wegener
Siegfried, Hameln, Germany, *Head R&D.*

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

Alistair Wotherspoon
CRB, *Senior Process Utilities Engineer.*

Dr Gülbengü Yüksel
Tigen, *Head of Quality.*

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

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

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.

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 SIXsigma 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 Course Analysis in Cases of Instability

Self Inspection in Non-Sterile Manufacturing

Irene Heiderich, *Boehringer Ingelheim*

- Why Self Inspection - regulatory background
- Planning a Self Inspection
- Performing a Self 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

Bioburden Control in Non-sterile Drug Substance and Product Manufacturing – Risk Mitigation versus Microbial Testing

Dr Tony Cundell, *Microbiological Consulting*

- Pros and cons of risk mitigation or microbiological testing compiled - with view on microbial quality of pharmaceutical ingredient, formulation, manufacturing process, physicochemical properties, packaging, dosage and recipients of a drug product
- The types of microbiological compendial tests, sampling limitation and suitability for microbial enumeration and unacceptable microorganisms
- Case Study: The shortage of infant formula in the U.S. in 2022 due to a product recall for Cronobacter sakazakii

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 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 suatainability aspects under the regulation of GMP.

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

Does Sustainability stand only for Green GMP?

Ana Cláudia Pinho

Susana Lima, *Bial Portela*

- Whats Sustainability Means – 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 Bitotechnologie*

- 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

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 actions will be impacting the marketing authorization dossier ?
- Conclusion

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*

Manuel André Deuringer, *Lonza*

- 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 Challenges in Primary Packaging Materials

Pirkko Lahti, *Orion*

Regulatory demands for

- QC testing (routine, development)
- Extractables studies
- Leachables studies

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?

Mahboobeh Rastegar, *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.

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

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

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

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

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

Dr Hiva Hossein Tehrani, *CinnaGen*

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

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

Marta Rodríguez-Vélez, *Letipharma*

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

TARGET AUDIENCE

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

MODERATORS

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

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

Olaf Wegener, *Siegfried*
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

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

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

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

- 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

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.

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

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

APS with a Gloveless Robotic Filling Line – Best Practices and Lessons learned

Thorsten Häfner, *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

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

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*
Jörg Zimmermann, *Vetter Pharma-Fertigung*

Upgrade of H_2O_2 Decontamination System for Production of RABS Vial Filling Line

Kenan Kanmaz, *Metall+Plastic*
Pasquale Cataldo, *Roche Diagnostics*

- 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

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

Julian Petersen, *groninger & co.*
Thorsten Häfner, *PSM*

- 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

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?

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

Katharina Schlereth, *Labor L+S*
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

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, *University Hospital of Regensburg*

- 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*

Fulfilling GMP Requirements for new Facilities vs older Facilities

Daniela Jahn, *Boehringer Ingelheim RCV*

- Layout designs and layout requirements for GMP facilities have changed over the time. Therefore, older facilities are regularly upgraded to comply with the current standards
- Inclusion of Good Engineering Practice to a risk based clean room qualification approach
- Requirements according to new Annex-1: risk based approach for requalification of non-sterile areas
- The path forward to sustainability: clean air downregulation at non-working hours as an example

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.

HVAC-System Design for a High Potent Facility

Nikolaus Ferstl, *University Hospital of Regensburg*

- 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 Lourenco, *NNE*

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

Case Study IPA Fraunhofer: Horizontal vs. vertical unidirectional Airflow Direction

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

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

Enabling ML Applications by a "Data Expert Team"

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

- 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

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 Daniel Samson, *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

Predictive Control of Titer/Yield & Quality for Biomanufacturing

Dr Hadj Latreche, *F. Hoffmann-La Roche*

- Apply Advanced Analytics to enable predictive Titer/Yield & Quality and reduce variability while increasing throughput and quality robustness in a GMP environment
- In-Flight predictive and adaptive process oversight for shop floor to target Titer/Yield & Quality Golden Batches
- Prove the value of utilizing Advanced Analytics as a digital product leveraging different data sources and advanced predictive algorithms
- Build site future capabilities required for a sustainable way of working using Advanced Analytics

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

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

Dr Helen Sauter, *Vetter Pharma-Fertigung*

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, *MESA FRANCE*

- 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 Andrea Kühn-Hebecker, *CONCEPT HEIDELBERG*

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, *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

Continuous Freeze Drying

Dr Friedrich Haefele, *formerly Boehringer Ingelheim Pharma*

Freeze drying in Food and Pharma

- Market survey
- Batch process lyophilization
- Applications for continuous lyophilization
- Outlook

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)

Alexandra Stärk, *Novartis*

- 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

Quality and Regulatory Strategies for the successfull Registration of an ATMP

Yogesh K. Davé, *Cypress Quality Consultancy*

- Understanding of Cell and Gene Therapy Products
- Autologous vs. Allogenic
- Is CAR-T the same as stem cell transplant?
- Pros and Cons of each therapy

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

Distributed Manufacturing for T-Cell Therapies

Dr Gülbengü Yüksel, *Tigen*

- Difficulties with centralized production
- Development of distributed manufacturing for clinical and commercial supply
- Regulatory hurdles with distributed manufacturing

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

Contamination Control Strategy (CCS) for ATMPs

Marsha Steed, *Resilience*

- 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

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

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, *Leukocare*
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

Biopharma Use Cases applying Process Analytical Technology (PAT)

Dr Veronika Nindl, *VTU Engineering*

- Implementation of biomass sensors for an accurate in-line analyses and an on time process control
- Establishment of DLS as an in-line impurity check to increase the clearance of hcDNA and HCPs prior protein A chromatography and thereby enhance purification
- Total protein determination of an inhomogeneous precipitation flow through for and automated protein concentration adjustment

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, *Leukocare*

- 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, *Blue Sky Process Engineering*

- 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

Vaccine Lot Release – Regulatory Aspects

Alya Aldahash, *SFDA*

- WHO guidance for Vaccine lot realms for national regulatory authorities
- Summary lot protocol
- Trend analysis and monitoring
- What the regulators expect from the manufacturer

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, Darmstadt, 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

Easy Registration

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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.

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The GMP PharmaCongress Tracks	Participation on 19 March 2024 ☐	Participation on 20 March 2024 ☐
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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