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GMP–PHARMA CONGRESS

#sharing challenges and solutions in practice

28/29 March 2023, RheinMain CongressCenter Wiesbaden

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Tracks

Aseptic Manufacturing & Technology
Barrier Systems / Robotics
Sterile Filtration / PUPSIT
Pre-Filled Syringes (PFS)
Digitalisation
Handling of Highly Active Products
ATMP – Manufacturing, Quality, Safety

CONCEPT HEIDELBERG
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Overview

The guiding theme of the PharmaCongress 2023 on 28/29 March will be „users sharing challenges and solutions in practice". Therefore, benefit from your colleagues' experience and from the direct information exchange at PharmaCongress & PharmaTechnica 2023.

The Tracks

As a participant you can switch between any of the tracks any time and also visit the PharmaTechnica Expo with more than 100 international exhibitors.

The PharmaCongress Tracks	28 March 2023	29 March 2023
Aseptic Manufacturing & Technology	✓	✓
Barrier Systems / Robotics	✓	✓
Sterile Filtration / PUPSIT	✓	✓
Pre-Filled Syringes (PFS)	✓	✓
Digitalisation	✓	✓
Handling of Highly Active Products	✓	✓
ATMP – Manufacturing, Quality, Safety	✓	✓
PharmaTechnica Expo	✓	✓

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 100 international exhibitors.

Fees

€ 690,- **for the one day ticket** plus VAT (until 31 January 2023 only € 590,- 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.

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Location

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

Contacts – Tracks

For questions regarding the content of the tracks:

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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 print-outs 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.

Keynotes

28 March 2023

Comprehensive Transformation of DR. KADE's Sites and Supply Chain

Dr Norbert Marquardt, Dr Kade Health Care

Sharing our experience with anyone embarking on a major TechOps restructuring effort

- What we did and how we did it
- Challenges and obstacles – expected and surprising
- Success factors and lessons learned

29 March 2023

Trends in Aseptic Manufacturing: Questions and demands for Pharma Machine Vendors

Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma

Pharma Manufacturers need to act on challenges from global demographic trends, changing economics, climate change and scarce resources. Post Covid-19- pandemic is Pre XYZ-pandemic. New regulatory requirements like EMA´s Annex 1 need to be adressed.
Technological breakthroughs are key to resolve many of these issues.
In my presentation I want to rise questions and demands to Pharma Machine vendors to drive technological improvement and to look for potential solutions.

Live Demos

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 at **www.pharmatechnica.com**.

Exhibitor	Live Demo
MK Versuchsanlagen	TBN
Optima pharma	Advanced technologies of Isolator systems with integrated aseptic transfer solutions (RTP) from METALL+PLASTIC & CASTUS
Bausch & Ströbel	OMNIA – The central platform for everything to do with Bausch+Ströbel machines
PHARMAPLAN A	Accelerated Design Decisions enabled by Digital Twins
IWT / Tecniplast	High pressure washing in the pharma enviroment
OCTUM	Vial inspection: classical machine vision vs. deep learning
ZETA	ZETA Sterile Connectors - For connecting separate fluid paths
Beratherm	Process Monitoring Derouging & Passivation
STÄUBLI TEC-SYSTEMS	How Robotics can support laboratory in a very compact space
Tempris	Tempris PAT Tool for the Implementation of Pharma 4.0 in Lyophilization
Ellab	EMSuite® - Monitoring Next Generation
Pall Biotech	Palltronic® Flowstar V Integrity Test Instrument Taking Filter Integrity Testing to the Next Level
Steriline	AN INNOVATIVE SOLUTION TO REDUCE PARTICLE GENERATION IN PRIMARY PACKAGING
Alfa Laval Mid Europe (Germany)	CultureOne Single-Use Separation in Bio Pharma
Merck	Annex 1 and sterile filtration - how to keep flexibility and regulatory compliance.
VITRONIC	Automated Visual Inspection In-Line: 360° Inspection of Vials Seals

Speakers

The following speakers already have confirmed their participation (constantly updated):

Dr Rüdiger Alt
Novartis, *Qualified Person for AT(I)MPs*

Raquel Arenós
INIBSA, *CMO-Dental Anaesthesia*

Dr Katja Aschermann
Tetec, *Vice President Quality*

Thomas Bach Nielsen
Novo Nordisk, *Director for Robotics & Operational Technology*

Gunter Bechmann
Pfizer, *Senior Manager Operations / Manufacturing*

Detlef Behrens
University of Applied Sciences Gießen / Philips University Marburg, *Lecturer for Quality Management*

Dr Simone Biel
Merck KGaA, *Senior Regulatory Consultant Life Science | Quality and Regulatory Management*

Dr Simone Bläsi
F. Hoffmann-La Roche, *Validation Expert*

Oliver Bosch
Epista Life Science Deutschland, *Head of Consulting*

Patrick Büschor
Cutiss, *Deputy Qualified Person*

Markus Busch
Vetter Pharma-Fertigung, Germany, *Manager Technology & Process Transfer*

Matthias Buttazoni
Ortner Reinraumtechnik, *CTO*

Ercan Cetin
Janssen Cilag, *Senior Engineer in Technical Operations*

Jean-François Decoster
UCB, Belgium, *Director & Head of Devices & Delivery Systems Science*

Vincent Delferriere
GSK, *Senior Manager TLCM IM Single Use*

Dr Frank Deisel
Tempris

Lizar Duhoki
Chemgineering Germany

Radek Fialka
Oncomed, PLIVA/Barr/TEVA Group , Czech Republic, *Board of Directors Member*

Dr Andreas Flückiger
Formerly F. Hoffmann La-Roche, Formerly Head of the Occupational Health Services of the Roche Group

Dr Filipe Gaspar
Hovione, Vice President, Technology Intensification

Bernd Geis
Managing Partner Process

Dr Nadine Gerlach
Lonza, *Senior Teamlead Operations, PCP*

Rainer Glöckler
swissfillon, *CTO*

Dr Rainer Gnibl
Local Government of Upper Bavaria, *GMP-Inspector for EMA and local Government*

Christoph Göhring
Janssen Cilag, *Sr. Quality Systems Specialist für Quality Risk Management*

Manuel Grund
Roche Pharma, *Process Engineer on Parenteral Launches and New Technologies*

Stephane Gumy
PMF, *General Manager*

Dr Friedrich Haefele
Formerly Boehringer Ingelheim Pharma

Thorsten Haefner
PSM, *VP Business Development*

Susanne Hall
Vetter Pharma-Fertigung, Germany, *Director Secondary Packaging & AVI Projects*

Dr Sabine Hauck
Leukocare AG, *EVP Corporate Development*

Dr Armin Hauk
Sartorius Stedim Biotech, *Principal Scientist Extractables & Leachables*

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

Steve Hughes
BPL, *Technical support Manager*

Peter Huonker
FRÜH, Switzerland, *Head of Quality Management*

Maren Jahn
Vetter Pharma-Fertigung, *Manager Technology & Process Transfer*

Casten Jasper
Charles River Laboratories, *Director, Validations & Systems Operations Europe*

Kenan Kanmaz
Metall+Plastic GmbH, *Technical Sales Manager*

Kati Kebbel
Fraunhofer Institute for Cell Therapy und Immunology, *Head of Department GMP Cell and Gene Therapy*

Eva Kelly
ERA Sciences, *Director - Senior Consultant*

Speakers

Anja Koeleman
Vetter Pharma-Fertigung, *Consultant IT Core Solutions – Document & Quality*

Christoph Köth
Fresenius Kabi Austria, *Project Manager on Life Sciences projects*

Horst Koller
HK Packaging, Switzerland, *Consultant*

Guillaume Lesage
Merck KGaA, *Senior Technical Consultant MSAT Merck*

Dr Morcos Loka
Minapharm, *Training Manager & GMP Advisor*

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

Didier Meyer
DMCompliance

Christoph Möller
Burgwedel Biotech (MSD), *Sr. Specialist / Maintenance HH*

Steffen Mörler
CSL Behring, *Project Excellence Lead*

Dr Daniel Müller
GMP/GDP Inspector, Local Government, Germany

Stefan Münch
ECA DI&IT Compliance Interest Group, *Business Director Validation Körber Pharma Consulting*

Dr Rainer Nicolai
F. Hoffmann La-Roche, *Project Manager*

Milos Nikolic
Galenika, *IT Director*

Marick Paris-Cadet
Technip Energies, *Project Manager on Life Sciences projects*

Franck Pavan
GTP Nano, *Director*

Ana Cláudia Pinho
BIAL - Portela & C.ª, *Head of Quality Assurance*

Marco Reiss
Paul Ehrlich Institut, *Head of unit Controlling, Quality Management / Deputy head of unit of Press, Information*

Londa Ritchey
Pharmalex, *Quality Director*

Margarida Rosa
GenIbet Biopharmaceuticals, *Project Manager*

Vimal Sachdeva
WHO, *Senior GMP Inspector, PQT, RPQ, MHP*

Yves Samson
ECA DI&IT Compliance Interest Group, Kereon AG, *CEO & e-Compliance SME*

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

Luigi Scaffidi
Boehringer Ingelheim Pharma

Matthias Schaar
Novartis Pharma Stein

Dr Ute Schleyer
Vetter Pharma-Fertigung, *Project Manager, Site & Plant Development*

Jürgen Schmitz
GSK Biologicals, Director Quality Transformation Hub, System, Data and eCompliance

Prof Christa Schröder
University Albstadt Sigmaringen, *Professor for QA & Regulatory Affairs*

Marcel Schulze
PPT Pharma Process Technology, *Head of PharmaTech*

Robert G. Schwarz
FH Campus, Vienna

Dr Harald Stahl
GEA, *Group Director Application & Strategy Management*

Erik Steffensen
Novo Nordisk, *Senior Project Manager*

Dr Tim Stöveken
Merz Therapeutics GmbH

Dr Arno Terhechte
GMP inspectorate / Bezirksregierung Münster, Germany, *Medicines Inspector*

Dr Mohamad Toutounji
Molgenium, *Developing and manufacturing of ATMP*

Iwan Tresch
FischerSöhne, Switzerland, *CEO*

Klaus Ullherr
Syntegon, Germany, *Senior Product Manager, Syringes and RTU Containers*

Ralf Wagner
Optima pharma, *Sales Director*

Rudolf M. Weiss
Stäubli Tec-Systems GmbH Robotics, *Global Head of Pharma Robotics*

Dr Florian Witte
Boehringer Ingelheim Pharma

Fred Wulfgramm
Merz, *Head of Engineering Site Dessau*

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

Aseptic Manufacturing & Technology
28/29 March 2023

Objective

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

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice. It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / Technology

Programme 28 March 2023

Energy Saving in Class C Cleanrooms Through Reduced Air Change Rates - a Case Study From a Biotech Company

CASE STUDY

Detlef Behrens, University of Applied Sciences / Philips University

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

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

Single Use V Re-usable the Changing Face of Sterile Filling

Steve Hughes, BPL

- Current Practice
- Reason for change
- Development
- Testing
- Completion

What if Final Product Filtration is Not Possible? Challenges and Opportunities of Aseptic Manufacturing for Large Viruses

Margarida Rosa, GenIbet Biopharmaceuticals

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

Implementing of PAT Tool for Lyophilization

NN

Dr Frank Deisel, Tempris

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

Programme 29 March 2023

Preparing the Facility for Extended Global Markets – Case Study

CASE STUDY

Raquel Arenós, INIBSA
Londa Ritchey, Pharmalex

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

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

Steffen Mörler, CSL Behring

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

Flexible Solutions for Different Market Requirements

Rainer Glöckler, swissfillon
Ralf Wagner, Optima pharma

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

Relocation of a Capping Machine to an Existing Production Line and Insertion of an Automatic Vial Inspection (AVI)

Christoph Möller, Burgwedel Biotech (MSD)
Lizar Duhoki, Chemgineering

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

Innovative Ozone Decontamination Process Including Areas of Application and Practical Example

Bernd Geis, Managing Partner Process
Matthias Buttazoni, Ortner Reinraumtechnik

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

Critical Thinking and Risk Management in Construction Projects as a Means to maximize Value – a Template for new CR Site in Kaarst

Carsten Jasper, Charles River Laboratories

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

Airflow Visualization According to New Annex 1

Luigi Scaffidi, Boehringer Ingelheim Pharma

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

Barrier Systems / Robotics
28/29 March 2023

Objective

This is why you will benefit from attending this conference:

- Case studies from various pharmaceutical companies deal with the implementation, qualification and operation of Isolator, 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.

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.

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Retrofitting RABS - Upgrade to V-CRT

Dr Ute Schleyer, Vetter Pharma-Fertigung

- After Vetter had already built 4 new clean rooms with V-CRT technology, 2 clean rooms have been added
- These two clean rooms previously operated as RABS for several years before being upgraded to the V-CRT system
- Challenges and differences to the newly built cleanrooms to the retrofitted are presented

Process Automation in a Small Scale Aseptic Manufacturing Site for Clinical Trial Products

Dr Tim Stöveken, Merz Therapeutics
Marcel Schulze, PPT Pharma Process Technology

- Presentation of flexible manufacturing concept for sterile liquid products for clinical trials
- Filling of small batches with automation of the most critical processes
- Implementation of Isolator technology into an existing building
- Training and operation concept in a non-routine environment

Replacement of H_2O_2 Generator from Existing Vial Filling Line

Dr Simone Bläsi, F. Hoffmann-La Roche
Kenan Kanmaz, Metall+Plastic

- Project challenge from the first step – timeline
- Production shutdown and realization
- Risk and other key tasks of upgrading
- Results of cycles development with the new H_2O_2 Generator RG4
- Key features and advanced technologies of RG4 - H_2O_2 Generator
- DECOpulse® - effective H_2O_2 Bio-decontamination System

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Barriers & Robotic Isolators in New Annex 1 (2022 version)

Dr Daniel Müller, Local Government, Germany

- Requirements for barriers/ isolators
- Major changes for barriers (version 2008 vs. 2022)
- How far are robotic isolators addressed?
- Challenges, discussion points & GMP inspector's view

Automated Thawing Process: Combining Robotic and Manual Process Steps

Maren Jahn, Vetter Pharma-Fertigung

- Concept: the path from process needs to first ideas
- Self-driving robot for the homogenization of frozen protein solution during thawing
- Technical Challenges: operator safety versus processing time; integration of specific robotic solution in mulit-use facility
- Implementation Challenges: Comparison of manual versus automated homogenization process of API bottles; integration in batch documentation; interaction between robot and operator

Disposable Isolator and Robotic Input, Why Not?

Frank Pavan, GTP Nano

- Introduction of fill and finish activities in grade A
- Use of 6 axes robots outside critical manufacturing area
- Use of Disposable filling Grade A isolator for parenteral manufacturing
- Containment of Highly potent products using Disposable isolator

New Methods to develop Pharma Automation and Robotic Solutions in Warp Speed

Thomas Bach Nielsen, Novo Nordisk
Rudolf M. Weiss, Stäubli Tec-Systems GmbH Robotics

Sterile Filtration / PUPSIT
28/29 March 2023

GMP–PHARMA CONGRESS

Objective

Reasons to attend this conference:

- You learn why PUPSIT found its way into the revised EU GMP Annex 1
- Inspectors discuss what they expect from the implementation of PUPSIT in pharmaceutical companies
- Pharmaceutical companies present their strategy for PUPSIT implementation in case studies

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with sterile filtration and especially PUPSIT in their daily practice.
It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / Technology

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PUPSIT, or Not to PUPSIT....?

Dr Simone Biel, Merck

Since the first draft of the new Annex 1 was published, the pre-use post-sterilization integrity test (PUPSIT) of a sterile filter was one of the most discussed topics related to the Annex 1 revision.

- How to interpret the Annex 1 PUPSIT clause?
- Why is it a debate?
- And what is the industry's answer on PUPSIT?

Practical Aspects of Pupsit Implementation

Guillaume Lesage, Merck

Intricated with PUPSIT are several technical challenges related to the preparation of filtration systems:

- Dry leak testing, flushing dynamics, Integrity test selection and dilution/drying challenges.
- Filtration assembly characterization insights
- Filter integrity test limits specific to single-use assembly.

Case Study Janssen Cilag: Pre-Use Post Sterilisation Integrity Testing (PUPSIT)

CASE STUDY

Ercan Cetin, Janssen Cilag
Christoph Göhring, Janssen Cilag

- Understanding PUPSIT
- Evolution of industry and regulatory positions
- PUPSIT vs. Non-PUPSIT, Risk based decision taking
- Works from the SFQRM BioPhorum / PDA Consortium
- Points to consider in PUPSIT Execution

PUPSIT – Annex 1 - Application of Risk Management

Dr Philip Hörsch, Vetter Pharma-Fertigung

- Risk Assessment for PUPSIT and Considerations of Associated Risks in Established Processes
- Risks of flaw masking and filter damage
- Product and process evaluations, process constraints?
- Risk-Benefit analysis

Case Study Boehringer Ingelheim Pharma: PUPSIT Risk Assessment: The Impact of Equipment Design

CASE STUDY

Dr Florian Witte, Boehringer Ingelheim Pharma

- Case study Boehringer Ingelheim
- PDA risk-based approach
- Holistic risk assessment including equipment design

Podium Discussion on PUPSIT

Dr Simone Biel; Dr Rainer Gnibl; Dr Daniel Müller

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Case Study Roche Diagnostics: Pre-Use Post Sterilisation Integrity Testing (PUPSIT) in the Revised Annex 1 - Friend or Foe of the Pharmaceutical Entrepreneur?

CASE STUDY

Manuel Grund, Roche Diagnostics

- Everything was better in the past... or was it? - An overview of the regulatory changes
- PUPSIT and its scientific raison d'être
- The process and the product - Which aspects play a major role?
- Quality Risk Management in application

Case Study GSK: PUPSIT – From Design to Implementation

CASE STUDY

Vincent Delferriere, GSK

- Regulatory environment around PUPSIT
- Design of Single Use Solution (from Generic to custom)
- Technical Implementation challenges
- Extractable approach
- Automation equipment
- Supply challenges

Case Study Novartis Pharma: PUPSIT – YES or NO?

CASE STUDY

Matthias Schaar, Novartis Pharma Stein

- What does Pre-use Post sterilization integrity testing (PUPSIT) mean?
- What do the guidelines say?
- What are the challenges, benefits and disadvantages for implementation?
- So, what to do?

Pre-Filled Syringes (PFS)
28/29 March 2023

Objective

In this course 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.

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

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Regulatory Overview, Annex 1 Impact and Inspection Experience

Dr Daniel Müller, Local Government, Germany

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

Tubs and Nests

Iwan Tresch, FischerSöhne

- Production process with its challenges from the raw material until a "RTU-Tub" ready to fill
- Requirements according to ISO 11040 – 7
- Further developments on Tubs and Nests

Image: COP

PFS made from Glass or Polymer

Horst Koller, HK Packaging

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

PFS and Needle Safety Systems

Horst Koller, HK Packaging

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

Fill-Finish Processes for prefilled Syringes

Markus Busch, Vetter Pharma-Fertigung

- Technology Overview
- Bulk syringes
- Pre-sterilized syringes

Device Assembling and Control Processes for Auto Injectors

Susanne Hall, Vetter Pharma-Fertigung

- What do you have to think about before selecting a device
- Impact of the Primary packaging material
- Assembling and Final Packaging
- Scale up process
- Inline Controls, Function and Release Tests

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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

High speed Syringe Filling Line for Oncological Drugs – Challenges & Solutions

Radek Fialka, Oncomed
Klaus Ullherr, Syntegon

- Project setup
- Choice of filling line and isolator
- Learnings from the mock-up study
- Integration into the building
- Strategy for filling toxic drugs
- Special challenges when filling toxic drug into syringes
- Use of NTT (No-Touch-Transfer) with fully automatic bag opening for inner and outer bag

Image: groninger

Visual Inspection

Jean-François Decoster, UCB

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

Sterile Secondary Packaging: Case Study

CASE STUDY

Peter Huonker, FRÜH

- Basic Process Overview
- Components
- Assembly
- EO Sterilization

Silicone-free Primary Packaging Materials in Filling & Stopper Process Development – Challenges & Opportunities

Manuel Grund, Roche Diagnostics

- Glass vs. COP - what are the differences?
- Viscous solution, high-speed filling and vacuum
- Process-technical requirements for NC vacuum stoppering
- Helium leakage testing

Digitalisation
28/29 March 2023

Objective

Reasons to attend this conference:

- You will get an overview of current digitisation trends 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.

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 projects.
It particularly addresses the departments:

- IT
- Production
- Quality assurance
- Engineering / Technology

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Introduction: Digitalisation in GxP environment: Between Mantra and Reality

Yves Samson, ECA DI&IT Compliance Interest Group
Stefan Münch, ECA DI&IT Compliance Interest Group

- Inhibitors
- Triggers
- Enablers
- Pitfalls

Digitalisation from the Inspector's Point of View

Dr Arno Terhechte, GMP Inspectorate / Bezirksregierung Münster, Germany

Case study – Digitalisation for Construction Management of Large Biopharmaceutical Plant

CASE STUDY

Marick Paris-Cadet, Technip Energies

- Case study: on-going construction site for a large biotech project localized in north of France, > 500M€ investment
- Coordination between client, engineering company, multiple subcontractors (60+)
- Methodology & Digital tools used for studies management and construction management
  - Collaborative BIM for 3D model, synthesis activity
  - Construction workfront/schedule, digital solution for on-site supervision for construction, inspection...
- Feedback & Added value
- Way forward: road map to full digitalisation, virtual reality / augmented reality

Influence of Digitalisation on the Future Work of Quality Departments

Jürgen Schmitz, GSK Biologicals

- From Paper to Data
- Critical thinking
- Review by exception
- From control to continued improvement to Digital Twin
- Validation today and tomorrow
- What will change for Quality?

Automated Validation - Enabling Better Data Reliability and Integrity in Life Sciences

Eva Kelly, ERA Sciences

- System agnostic presentation discusses the increased use of automated validation solutions
- Reduction in manual transcription Errors
- Centralized management of validation documents and records
- Effort Commensurate with risk - ability to leverage unscripted, scripted and exploratory testing
- Configuration to address True Copy Record concerns

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Advanced Monitoring of Production Process Using IIoT System

Milis Nikolic, Galenika

- Current challenges with efficiency and monitoring production process
- Identifying critical points in the process
- How IIoT systems can help
- System Demonstration

Are Digitalisation and Artificial Intelligence a Double-Edged Sword in Pharma and Healthcare?

Marco Reiss, Paul-Ehrlich-Institut

- 'What is really meant with digitalisation and AI in pharma and healthcare?
- New perspectives and chances of digitalisation and AI in a hyperconnected pharma and healthcare sector
- Impact and (potential) risks of further digitalisation on the field of pharma and healthcare
- Do we need a guiding framework? Critical reflections, overthinking

Digitalisation and Automation: How to Avoid Losing from Day One, Preventing Successful Transformation to Fall Short

Ana Cláudia Pinho, BIAL - Portela & C.ª

Many transformations are addressed as Digital Transformations instead of business transformations.

- Planning transformation
- Rethink processes
- Use automation to avoid inefficient use of resources

Implementation of Pharma 4.0 at the German CDMO PSM GmbH

Thorsten Haefner, PSM

- Complete paperless pharmaceutical production
- Generation of real-time data for faster batch releases
- Use of virtual twins for higher productivity
- Use of robotics for better process monitoring
- Elimination of humans for repetitive and critical process steps

AI Supported Intervention Detection and Classification in the Aseptic Core

Christoph Köth, Fresenius Kabi Austria

- FrEDIS - Fresenius Event Detection Information System is a pilot system live in routine production which in the current setting allows the detection and classification of human interventions in the aseptic core
- The development of such a system not only lead to new insights into aseptic manufacturing but also required an innovative (XAI based) approach to better understand AI decisions. This approach also enables a GMP validation where AI no longer acts as a black box
- Depending on the project progress results of discussions with relevant authorities should be available at the date of the conference

CASE EVENT with a German CMO – Moving Quality Documents to the Cloud

CASE STUDY

Anja Koeleman, Vetter Pharma-Fertigung
Oliver Bosch, Epista Life Science Deutschland

- Needs analysis and system selection
- Process optimization
- Validation
- Organisational Change Management

Handling of Highly Active Products
28/29 March 2023

Objective

Main focus of this conference is on the connection of cGMPs with safety aspects, especially on avoiding cross contamination and minimizing exposure. Recently completed projects and facilities for the production of highly potent products demonstrate the state of the art.
It will also deal with exposure & cleaning validation limits and the possibilities offered by containment technology, shown by real life examples from pharmaceutical industry including oral solid dosage forms and sterile medicinal products.

Target Audience

This conference aims at persons from production, engineering and quality, responsible for

- Design of new manufacturing areas
- Operation of processes containing highly potent material
- Occupational safety
- Cleaning concepts and contamination prevention

as well as engineering and plant-construction companies working in containment projects.

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Principles of Assessing and Managing Occupational Health Risks in Potent Compound Handling

Dr Andreas Flückiger, formerly F. Hoffmann-La Roche

- Legal requirements regarding worker safety
- Assessing the hazard: potency and toxicity of the compounds. Occupational exposure limits and exposure bands
- Ensuring the right level of process containment: Design exposure limits as drivers for equipment selection. The illusion of "closed processes"
- Setting of health-based exposure limits and process containment: great benefits for GMP

Exposures to pharmaceuticals at the workplace must be controlled to below acceptable limits. For most APIs, the manufacturer himself needs to develop these limits, and compliance with them must be documented. Protection of the workers from overexposure must be achieved primarily by technical means and not by means of personal protective equipment. Equipment must have adequate containment so that the required exposure control is ensured at least in all routine situations. Existing facilities must be upgraded accordingly. The toxicological and pharmacological basis of assessing APIs with the objective of worker protection is the same as the one justifying GMP cleaning criteria and acceptance of multi-product use of a facility. Primary process containment is the key tool for the prevention of airborne cross-contamination and via the one by mechanical transfer.

Review of Technical Requirements for contained Product Handling

Dr Harald Stahl, GEA

- Product transfer- review of current possibilities
- Sampling 1 - Review of possibilities for contained sampling
- Sampling 2 - Examples for in-line measurements allowing to drop sampling
- Cleaning: Examples of automatic cleaning

Case Study Pfizer: Constructional and regulatory Challenges of an OEB 4 Manufacturing Site

CASE STUDY

Gunther Bechmann, Pfizer
Prof Christa Schröder, University Albstadt Sigmaringen

Special requirements have to be considered for planning and construction of buildings intended for manufacture of highly potent medicinal products

- Implementation of special GMP Requirements
- Special staff training
- Environmental aspects

GMP Inspection Experience of Products containing hazardous Substances & Introduction to WHO's Prequalification Program

Vimal Sachdeva, WHO

- WHO Prequalification (PQ) history and process
- WHO PQ of pharmaceutical products containing hazardous substances
- GMP-compliant handling of hazardous substances
- Challenges during GMP inspections

Case Study Hovione: Spray Drying and Continuous Tableting of highly active Materials

CASE STUDY

Dr Filipe Gaspar, Hovione

- Relevance of Spray Drying and Continuous Tableting in the Pharmaceutical Industry
- From risk assessment to lab development and to commercial manufacturing
- Specific requirements for Spray Drying and Continuous Tableting
- Examples of lab to commercial units capable of handling potent APIs

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Cross Contamination Control Strategy in Light of the new Annex I

Robert G. Schwarz, FH Campus, Vienna

- OHS-requirements and CCS according to the new Annex 1
- Cross Contamination Control - the unseen stepchild of them with maybe a high potent habit
- How to implement a compliant CCS with Containment requirements properly
- "Close, closer, isolator - but what about RABS?" - Question from the desperate pharmacies

CASE STUDY

Case Study Merz: Production of sterile & highly potent Products

Fred Wulfgramm, Merz

Handling of Solids with Single-Use Systems in the chemical Synthesis of highly active Substances

Dr Rainer Nicolai, F. Hoffmann-La Roche

- Available Equipment & Technology
- Pros and Cons of Single-Use Systems
- Case Studies: Experience with SUT in chemical synthesis of highly active substances

State-of-the-art Continuous Tableting equipment, Hovione Sete Casas, Portugal

CASE STUDY

Case Study Lonza: Use of Single-Use Equipment for the commercial Production of highly potent ADCs

Dr Nadine Gerlach, Lonza

- Challenges in the production of ADCs (Antibody drug conjugates)
  - GMP aspects
  - Personal safety
- Current challenges in the use of single use components in the pharmaceutical industry
  - Multisourcing
  - Qualification of single-use materials
- A look into the future: Single-use equipment in ADC production

CASE STUDY

Case Study Minapharm: Design of a HPAPI Biomanufacturing Facility

Dr Morcos Loka, Minapharm

- How to apply risk management in the design of a facility for biopharmaceutical HPAPIs
- How to achieve compliance with US & EU GMP and EHS requirements
- What controls can be applied regarding equipment closure, flow of materials and personnel, waste management, cleanroom, HVAC
- How to set a suitable containment strategy
- What are the possible challenges and how to overcome
- How to quantitatively evaluate the effectiveness of these controls

New approach for assessing Dust-Retention Performance of high-containment Systems

Dr Andreas Flückiger, formerly F. Hoffmann-La Roche

- Continuous or periodic dust emission monitoring. Results in µg/m³.
- Early detection of otherwise unnoticed leakage
- Intervention before worker exposures become too high

High containment systems have generally been tested for their containment performance, for example based on ISPE's "SME-PAC" guide. This reflects the design and performance of the equipment as it leaves the factory of its manufacturer. Over time, these systems may lose some of their containment capability, and this is often not visible to the naked eye. The Digital Canary is a system to continuously or periodically monitor dust emissions with the objective to detect leakage before it becomes critical for worker safety. Contrary to a particle counter, it delivers the results in µg/m³. The results can serve as a trigger for preventive maintenance and can replace costly substance-specific industrial hygiene sampling. The system is compatible with a range of solid dosage applications. The Digital Canary is being developed for additional uses.

ATMP – Manufacturing, Quality and Safety
28/29 March 2023

Objective

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.

Target Audience

This conference is aimed at all persons who

- are involved in the extraction and manufacture of Cells, Tissues and ATMPs
- are responsible in 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

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Vectors for ATMPs – Stabilization by Formulation Development

Dr Sabine Hauck, Leukocare

- Algorithm based formulation development and in silico long-term prediction
- Stabilization of viral vectors beyond the expected
- The next generation: LNPs as vectors

ATMP: Market, Manufacturing and Challenges

Dr Mohamad Toutounji, Molgenium

- Global market overview of ATMP
- ATMP Clinical trials
- Advanced manufacturing processes and scalability
- Development of new methods for quality control of ATMP
- Regulatory pathways and challenges

GMP for ATMP

Dr Rainer Gnibl, Government of Upper Bavaria

From Process Transfer to clinical / commercial Manufacturing of Cell and Gene Therapy Products – Experiences of a CDMO

Kati Kebbel, Fraunhofer Institute for Cell Therapy und Immunology

- Execution of Process transfer / process setup from CDMO point of view
- Interaction in a pharmaceutical system
- Process documentation and Manufacturing license
- Exemplary challenges of a CDMO like raw materials, ramp up, phase out

Cell based ATMPs: A Success Story

Dr Katja Aschermann, TETEC

- Tissue engineered products
- Regulatory Landscape
- Challenges of autogenous cell-based ATMPs
- Case study: Novocart® Inject

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Individual stringent Mini Isolators for autologous Cell Therapy

Didier Meyer, DM

- Common Strategy to avoid Cross Contamination
- A decentralised scale-out concept to be implemented in hospitals
- How a dual temperature Class C or D decentralised platform of a maximum of 10 mini-isolators from donor/patient leukapheresis allows within one to three weeks to take care of more than 100 patients a year using CAR- T techniques and making it affordable

Case Study: QC Test Profile and Release Strategies for ATMP

CASE STUDY

Patrick Büschor, Cutiss
Stephane Gumy, PMSystems

- The QC profile of ATMPs
- The challenges of releasing extemporaneous ATMPs
- Different release strategies for ATMPs (extemporaneous finished products, reconstitued vaccine, ...)
- The use of potential contaminated ATMPs or OOS products in the frame of clinical trials

Exceptional Provision of AT(I)MPs affected by OOS Results

Dr Rüdiger Alt, Novartis

- Introduction & regulatory framework
- Process and workflow for exceptional provisions
- Health Authority interactions
- Opportunities and limitations of chapter 11.5

Freezing and Thawing

NN

Establishment of Quality Management System (QMS) for Cell Therapies

Erik Steffensen, Novo Nordisk

- Cell therapies - When living human cells are the pharmaceutical product
- Similarities and differences between conventional medicines and cell therapies from a scientific and regulatory point of view
- To what extent considerations from the development and manufacture of conventional medicines and biologics can be used in the design of the QMS for cell therapies
- Design principles and the implementation of a QMS for cell therapies

The Assessment of Process Equipment Related Leachables in Cell and Gene Therapies

Dr Armin Hauk, Sartorius Stedim Biotech

- The specialties with extractables and process equipment related leachables (PERLs) in cell and gene therapy
- Exposure estimations for therapeutic cells and patients established with PERL-model calculations and digital twins
- The use of a high throughput cell painting assay to screen for toxic and/or detrimental effects of PERLs on therapeutic cells

Easy Registration

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Congress Dates

Tuesday, 28 March 2023, 09.00 - 18.00 h
Wednesday 29 March 2023, 09.00 - 17.00 h
Registration
Tuesday & Wednesday, 28/29 March 2023, 08.00 - 09.00 h

Location

RheinMain CongressCenter (rmcc)
Friedrich-Ebert-Allee 1
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Fees

The one day ticket is available for € 690,- plus VAT (until 31 January 2023 only € 590,- 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, 28 March is included; please mark if you would like to attend the Social Event.

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The PharmaCongress Tracks	Participation on 28 March 2023 ☐	Participation on 29 March 2023 ☐
Aseptic Manufacturing & Technology	☐	☐
Barrier Systems / Robotics	☐	☐
Sterile Filtration / PUPSIT	☐	☐
Pre-Filled Syringes (PFS)	☐	☐
Digitalisation	☐	☐
Handling of Highly Active Products	☐	☐
ATMP – Manufacturing, Quality, Safety	☐	☐
Participation in Social Event	☐	n.a.
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