Part of PHARMA TECHNICA

European Aseptic Conference 2021

21 - 22 April 2021
Online Conference and Exhibition
– Registration free of charge –

Highlights

/Current cGMP Requirements in Aseptic Manufacturing
/Robotic Solutions
/Lyophilization
/Optimization of Processes and Production Lines
/Blow-Fill-Seal-Technology Goes Digital
/Transfer of Equipment and Components
/Fully Automated Pilot Plan

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Aseptic Conference

Dear Colleague,

We would like to invite you to our international conference on the aseptic production of medicinal products.

Due to the Covid-19 pandemic, no congresses and trade fairs can be organised. But how can we keep you informed about the state of the art in FDA/GMP compliant Aseptic Manufacturing? We have decided to develop a solution that allows the latest developments in sterile and aseptic manufacturing in pharmaceutical and biopharmaceutical production to be offered efficiently online. And all this free of charge for the participants.

The virtual PharmaTechnica 2021 will only be held once. In 2022, we will organise the PharmaTechnica exhibition and conferences in the Congress Centre again. So take advantage of this unique opportunity and inform your colleagues about this offer.

We have invited the leading suppliers of technological solutions in the field of sterile and aseptic manufacturing to inform about the recent developments of technology. There will also be virtual exhibition stands where you can ask the experts your questions via chat (text or video).

We are looking forward to your visit. Register in time to secure your access to the conference and exhibition.

With kind regards

Oliver Schmidt
General Manager
Concept Heidelberg

Objectives

The aseptic production of medicinal products is the "supreme discipline" in pharmaceutical and biopharmaceutical production. High demands are set on the processes and technologies. The regulatory requirements of the EU/EMA and the US FDA are high and subject to constant development. Not least due to the current revision of EU GMP Annex 1 for sterile production, suitable technical solutions must be found.

But not only EU/FDA GMP compliance is important. In addition technological concepts also have to focus on production efficiency. Short set-up and changeover times are important and save manual interventions in case of deviations have to be ensured. The aim of this conference is to present the current state of the art in the field of sterile/aseptic production.

Programme

Key Note Presentation: Aseptic Manufacturing for Biopharmaceuticals and Vaccine Manufacturing

Friederike Wedelich, GMP Inspector at the Regional Council of Tuebingen

- Applicable Guidelines
  - EU GMP Guidelines
    - EU GMP Guideline Part II
    - EU GMP Annex 1 (current Draft for revision)
    - EU GMP Annex 2
  - EMA Notes for Guidance (NfG)
  - The new PIC/S Aide Memoire - Inspection of Biotechnology Manufacturers
  - Others
- Experience from GMP Inspections of Biotechnological Companies
  - Focuses of Inspection
  - Typical Issues & Deficiencies

Smart Robotic Solutions in Aseptic Fill/Finish environments

Rudolf-Michael Weiss, Stäubli Robotics

- Challenges for robotic suppliers in the aseptic environment
- Case studies showing various solutions how challenges got solved
- What's next in pharma? Pharma4.0 and smart factory solutions

Robotic Nest Filling Line for Cartridges, Vials and Syringes

Mirko Ebeling, EbeTech / Steriline

- Decontamination of tubs
- Filling of different glass container - flexible portfolio
- Low oxygen filling of vials (<0,5% residual oxygen)
- General layout of the system

Injection Simulation Testing of Cartridges and Syringes

Jan Havemann, TesT and Horst Koller, HK Packaging Consulting

- Automated testing systems for your production site
- Glide force, break loose force and leakage test
- Technical and user perspective in dialogue

Refrigeration Technologies – Ready for the Future?

Jens Gemmecker and Fabian Plaum, Hof

- Refrigeration technologies today
- Climate-friendly pharmaceutical technology
- HOF CryoBlizzard

NIR Moisture Determination and 100% Vial Traceability Application of Freeze Dried Products

Johannes Selch, GEA Germany

- Introduction automatic loading and unloading
- Online NIR moisture determination with LYOSENSE®
- 100% vial inspection & traceability
- Continuous monitoring and full traceability of primary packaging with LYODATA®

Blow-Fill-Seal-Technology Goes Digital

Bastian Schellzig, Rommelag

- Outlook on Industry 4.0: Digital value creation for pharmaceutical manufacturing
- Platform-independent integration of external software tools without risk
- Increased productivity through automated data processing and visualization

Flexibility as a Key to Optimize (Sterile) Processes and Production Lines

Michael Kühneisen and Patrick Schösser, Bausch & Ströbel

- Flexible solutions in machine procurement
- Flexibility in expanding your production line
- Flexibility in your level of investment
- Flexibility in processing a variety of products and packaging materials
- Flexible process and machine solutions

Transfer of ATMP Bench Top Aseptic Process into Grade A, H_2O_2 Isolator Environment and how to Validate 6-log Decontamination

Martin Glättli, ProSys

- Ergonomic transfer of semi-automatic ATMP process into isolator
- Evaluation of suitable lab process equipment for Grade A environment and H_2O_2 decontamination
- Overcoming hurdles and final integration solutions
- Validation of process equipment for 6-log H_2O_2 decontamination

Stainless Steel DPTE® Beta Containers and Racks Safely Load, Sterilize and Transfer your Equipment and Components

Anis Kara, Getinge

- Getinge's comprehensive range of DPTE® Beta Container racks provides a suitable solution for your needs and adapts to your specific loads.
- Items are held securely in place inside the container enabling efficient and ergonomic loading and unloading of components, tools, etc. into a sterile zone.
- Complete access by steam during autoclaving, leaving no hidden zones so that steam and air can circulate efficiently.
- It is designed to provide support for standard to customized stainless steel containers.
- DPTE® Rapid Transfer Systems are used in most of the Industry Isolators and Filling Lines.

Design of a fully automated pilot plan

Georg Frinke, Ferring Arzneimittel

- New Robotic R&D Facility and required decisions to be done
- Constraints to be considered in a fast track project
- Advantages of flexible and fully automated fill-finish-platform for all kind of current product containers
- Maximum challenge due to additional TOX/High potent requirements

Customer Project from Syntegon

Turnkey Project for Aseptic Filling of Highly Potent Products

Ralf Wagner, Optima and Kenan Kanmaz, Metall + Plastic

- Comprehensive scientific process engineering for high potent products (integrated FAT, CFD simulation)
- Integrated concepts for highly potent products (pressure zone concept, wash down concept)
- Isolator design and return air filter concepts for highly potent drugs (Bag-in-Bag-out-Filter/ High Potent Filter)
- Machine design for highly potent products

Bioproduction & ATMPs: How to Better Drive your Performance & Productivity with Better Process and Microbiological Control

Felix Montero & Arnaud Paris, bioMérieux

- What are the quality failure risks ?
- How can a production process be better controlled ?
- What is the value of In Process Testing to improve productivity?
- Review of usable Automated & Rapid Microbial Methods (ARMM)

Draft Annex 1 Contamination Control Strategy for Barrier Systems like Isolators

Richard Denk, Skan

- Annex 1
- Contamination Control
- Isolator

BioPhorum Industry Proposal for Implementation of SUS Bag Assembly Leakage and Defect Toolkit

Donato Vasta, Merck

- Knowledge growth
- Training Program guidance
- Leak response guidance

continued on the next page

State-of-the-Art Glove Testing

Dr Christopher Keil, MK Versuchsanlagen und Laborbedarf

- 3rd generation Glove Testers
- GAMP 5, CFR 21 Part 11 compliant softward
- Half-Suit-and Transfer-System-Tester
- Glove Management and Reporting Tools

Presentation in German Language:

Inline-Inspektion reduziert teure Fehler in der Liquida-Abfüllung

René Purwin, Optonic

- GMP-konforme Inline-Prüfungen auch für Nachrüstungen
- Kontrolle von Stopfensitz/-typ, Bördelrand oder Aufdruck für unterschiedliche Vial-Formate
- Kompakte Lösungen, ohne zusätzlichen Flächenbedarf
- Prozesskonforme Optionen, von Audit Trail bis zur LDAP Integration und SCADA Anbindung

Cleanroom Textile Management - Digital Transformation and Looking into the Future

Hans-Jörg Kronberger, elis Cleanroom

- Technological innovations and changing customer expectations
- New solutions and organizational principles in the textile industry
- Data transparency and traceability
- Digitalization trends, e.g. automated dispensing solutions, daily traceability of garment items and access controls for cleanroom areas

PharmaTechnica - The Virtual Exhibition

The virtual PharmaTechnica is an exhibition exclusively for the pharmaceutical industry and offers you a unique opportunity! So, take your time to take a look at the latest products and services from the leading suppliers to the pharmaceutical industry – all of them specialized in the field of pharmaceuticals – simply and conveniently on your PC or tablet.

You can also take advantage of the presentations in the conference to get to know a specific product or service from a supplier. This is where the PharmaTechnica exhibitors present themselves in detail.

Learn more about the exhibitors this year on https://www.pharmatechnica.com.

Take Part in the Conference

Date of the Live Online Conference

Wednesday, 21 April 2021
Thursday, 22 April 2021
The detailed agenda with start and end time of each presentation will be announced soon.

Free Participation

Participation is free of charge for qualified experts from pharmaceutical and biopharmaceutical production environment.

Registration

Please register at https://pharma-congress.expo-ip.com/registrieren

Presentations

The presentations will be made available to you prior to the Live Online Training as PDF files.

Conference Language

The official conference language will be English.

Organisation and Contact

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