Part of PHARMA TECHNICA

CleanRooms in Life Science 2021

20 April 2021
Online Conference and Exhibition
– Registration free of charge –

Highlights

/Cleanrooms for Sterile Manufacturing - Hot Topics for Approval-Inspection
/Technical Planning
/Challenges in Transfer and Access
/Environmental Monitoring - Planning and Quality
/Disposables in Contamination Control
/Cleanroom-Compatible Textile Processing
/Disinfectant Efficacy Testing

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CleanRooms in Life Science

Dear Colleague,

We would like to invite you to our international online conference „CleanRooms in Life Science".

Due to the Covid 19 pandemic, congresses and trade fairs cannot be held locally. But how can you still keep up to date with the latest developments in cleanrooms and their ongoing operation? We have decided to develop a solution to efficiently offer the current trends in GMP compliant manufacturing in cleanrooms online. And all this free of charge for the participants.

The virtual PharmaTechnica 2021 will only happen once. In 2022, we will again host the PharmaTechnica exhibition and conferences in the Congress Centre. So take advantage of this unique opportunity and find out about current regulatory requirements for the construction, implementation and maintenance of cleanrooms and how they are implemented in practice.

We have invited representatives of the regulatory authority as well as the leading suppliers of technological solutions in this field to provide information on the current state of science and technology. There will also be virtual booths 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

Axel H. Schroeder (Dipl. Biol.)
Operations Director (Microbiology and Hygiene)
Concept Heidelberg

Objectives

In many industries, cleanrooms are indispensable for the production of high-quality products. In the life science sector, however, it is not only about product protection but also about user and patient protection. This means that the manufacturer bears a high level of responsibility for the well-being of many people.

Therefore, Cleanrooms in Life Science is concerned on the one hand with the official requirements, e.g. in the context of inspections of the cleanrooms and their maintenance, and on the other hand with the technical issues in the planning, installation and daily operation of cleanrooms. Current issues relating to the hygiene of rooms and personnel are also presented, up to and including the control of the operating status through environmental monitoring.

Programme

Sterile Facility: Hot Topics for Approval-Inspection

Rainer Gnibl, GMP Inspector Upper Bavaria

- Background: Annex 1 DRAFT
- What is essential?
- Inspector´s questions & expectations

Planning and Conception of a New Cleanroom/HVAC System

Speaker to be named

Initial Qualification

Jürgen Blattner, BSR

- Necessary Measurements
- Documentation (examples)
- Intervall of Measurements

Transfer in Aseptic Manufacturing via Autoclave – Possibilities and Pitfalls

Fedegari

Access & Transfer into Clean-Areas

Rainer Gnibl, GMP Inspector Upper Bavaria

- Personnel
- Material
- Airlocks
- Clothing

The Crux of Disposable Materials in Contamination Control

Carsten Moschner, Dastex

- General information on disposable articles in controlled areas
- Clothing
- Gloves
- Wiping products
- Conclusion

The Most Frequently Asked Questions about Clean-room-Compatible Textile Processing

Britta Heck & Jörg Mesenich, CWS Cleanrooms

- Validation of Laundering Procedures
- Possible effects of the new Annex 1 draft on garment systems
- Validation of garment systems
- Best Practice - Examples from the field

Disinfectant Efficacy Testing: Methodology and Approach to Validation

David Collins, Ecolab

- What is Disinfectant Efficacy Testing & the relevant regulatory expectations
- Phases of Disinfectant Efficacy Testing & their methodology
- Factors influencing disinfectant performance
- Validation points to consider & preparing for inspection

Solutions for Cleanroom Cleaning

Klaus-Peter Zepp, Profi-Con

- Cleanroom cleaning challenges
- Between error und simply not considered

Preparation of a Monitoring Plan for Surface and Personnel

Stephan Löw, CSL Behring

- Requirements of the regulations
- Frequency
- Determining the control points

Quality of Monitoring Data – A Lifecycle

Frank Panofen, PMS

- How to use data to feed today's knowledge and adapt to tomorrow's processes.
- Important considerations when developing a contamination control strategy, taking into account the data quality approach.
- How different systems such as an environmental monitoring system, data management software, LIMS and others can work together in a synergistic way to leverage data quality
- Solution strategy of PMS to create a flat and convenient patch pathway to speed up the product release process.

Speakers at the Conference

Dr Jürgen (Ing.) Blattner
BSR Ingenieurbüro

David Collins
Ecolab

Dr Rainer Gnibl
Government of Upper Bavaria

Britta Heck
CWS Cleanrooms

Stephan Löw
CSL Behring

Jörg Mesenich
CWS Cleanrooms

Carsten Moschner
Dastex

Frank Panofen
Particle Measuring Systems

Dr Klaus-Peter Zepp
Profi-Con

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

Tuesday, 20 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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