

# 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
- / Initial Qualification
- / Challenges in Transfer and Access
- / Cleaning and Disinfecting – Programm and Efficacy Testing
- / Environmental Monitoring - Planning and Quality
- / Disposables in Contamination Control
- / Cleanroom-Compatible Textile Processing
- / Disinfectant Efficacy Testing

# 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

### 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 Cleanroom-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

## Cleaning and Disinfection Program for Aseptic and Cell Gene Therapy: Best Practices to Prevent Microbial Contamination in Aseptic Core

*Walid El Azab, Steris*

- Learn the current best practices regarding cleaning and disinfection of hoods, RABS and Isolators.
- Understand the regulatory requirements and the potential impact of the draft Annex 1 revision in cleaning and disinfection program for hoods, RABS and Isolators.
- Learn from case study to convey industry best practices.

## 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



**Walid El Azab**  
Steris Corporation



**Dr Rainer Gnibl**  
Government of Upper Bavaria



**Britta Heck**  
CWS Cleanrooms



**Stephan Löw**  
CSL Behring



**Jörg Mesenich**  
CWS Cleanrooms



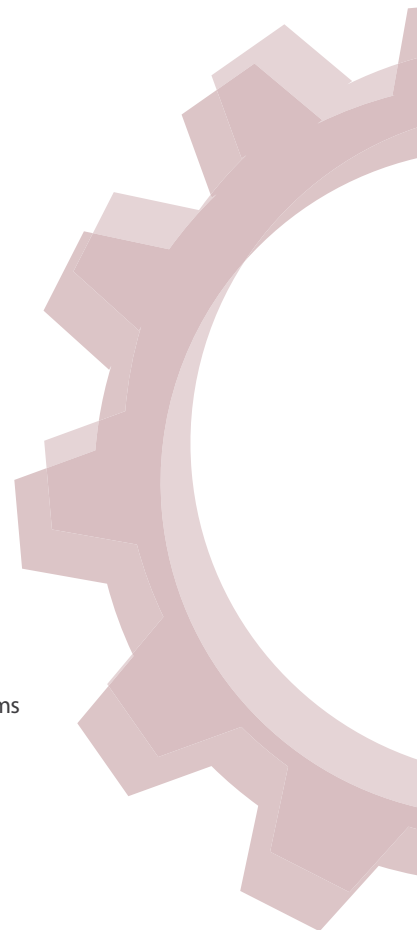
**Carsten Moschner**  
Dastex



**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

CONCEPT HEIDELBERG

P.O. Box 10 17 64

D-69007 Heidelberg, Germany

Phone +49 (0) 62 21/84 44-0

Fax +49 (0) 62 21/84 44 34

[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)

[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

#### For questions regarding content:

Axel H. Schroeder (Operations Director) at +49 (0) 62 21/84 44 10 or via email at [schroeder@concept-heidelberg.de](mailto:schroeder@concept-heidelberg.de).

#### For questions regarding organisation:

Mr Ronny Strohwald (Organisation Manager) at +49 (0) 62 21/84 44 51 or via email at [strohwald@concept-heidelberg.de](mailto:strohwald@concept-heidelberg.de).

