Modern Cleanroom Technology

Part of PharmaCongress 2024

19/20 March 2024
Wiesbaden, Germany

Highlights

- Current Zoning Concepts for GMP Cleanrooms
- New Requirements from Annex 1 for Cleanrooms & Barrier Systems
- Green GMP for Cleanrooms
- HVAC Systems Design for High Potent Facilities
- Setup of a CCS Strategy with HACCP
- Airflow Visualisation within the critical Zones
- Strategies for Cleanroom Testing
- Assessment of microbiological Contaminations in sterile Manufacturing
- Case Study Boehringer Ingelheim: Impact of the new EU Annex 1 in Practice
- Case Study Stulln Pharma: Design of a new Sterile Facility
- Case Study Fraunhofer IPA: Horizontal vs vertical unidirectional Airflow

Speakers

Nikolaus Ferstl | University Hospital of Regensburg, Germany

Daniela Jahn | Boehringer Ingelheim RCV, Austria

Dr Markus Keller | Fraunhofer Institute for Manufacturing Engineering and Automation (IPA), Germany

Dr Johannes Krämer | CSL Behring, Germany

Dr Lars Kreye | Boehringer Ingelheim Pharma, Germany

Doris Laçej | Profarma, Albania

André Lourenco | NNE, Denmark

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

Andreas Nuhn | D&B Pharmadesign, Germany

Luigi Scaffidi | Boehringer Ingelheim Pharma, Germany

Ruben van der Galiën | GE HealthCare, Netherlands

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GMP-PHARMA CONGRESS

This conference is part of PharmaCongress 2024

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GMP–PHARMA CONGRESS

MODERN CLEANROOM TECHNOLOGY

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 cleanrooms.

It is therefore essential to be aware of all restrictions and relations between material and personnel flows before starting with the building of cleanrooms 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.

PROGRAMME 19 March 2024

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 cleanroom 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 cleanrooms 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.

PROGRAMME 20 March 2024

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 Directions

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

SPEAKERS

Nikolaus Ferstl
University Hospital of Regensburg, Germany
Nikolaus Ferstl has a bachelor degree in mechanical engineering. He has almost 20 years of experience in the design of pharmaceutical facilities. He has been working for M&W (former LSMW), for example as deputy head of the subsidiary in Vienna. In 2009 he changed from the planning to the user's side as technical director of the University Hospital of Regensburg. He is also a freelance consultant for GMP engineering.

Daniela Jahn
Boehringer Ingelheim RCV , Austria
Daniela Jahn is Head of the Unit for process equipment qualification at BI RCV. Her team is responsible for qualification of equipment, cleanrooms and clean media systems. She joined Boehringer Ingelheim in 2016, her focus lies on harmonisation of internal processes and continuous improvement for a risk based qualification approach.

Dr Markus Keller
Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) , Germany
Markus Keller is project manager at the Fraunhofer Institute for Manufacturing Engineering and Automation (IPA), Department of Cleanroom and Microproduction. His area of expertise includes the qualification of equipment with regard to cleanroom suitability.

Dr Johannes Krämer
CSL Behring, Germany
Dr Krämer studied energy- and process engineering. He has the global responsibility for Maintenance & Utilities at CSL Behring. Before that he was head of the department Plant Engineering and Head of Engineering and Head of Maintenance & Utilities at the CSL site in Marburg.

Dr Lars Kreye
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Dr Kreye joined Boehringer Ingelheim as Head of Regulatory Compliance. Currently he is managing two aseptic filling lines as well as a packaging unit for final packaging.

Doris Laçej
Profarma, Albania
Doris Laçej is working for Profarma the largest pharmaceutical manufacturer in Albania. Since 2021 she is Head of sterile production for large volume parenterals. She is also trainer in collaboration with the University of Medicine (Faculty of Pharmacy).

André Lourenco
NNE, Denmark
André Lourenco has a B.Sc. in Mechanical Engineering, an MBA in Project Management and is an HVAC & Cleanroom Specialist Engineer at NNE in Denmark. He has more than 15 years of experience in design, evaluation, installation, commissioning, validation, balancing and testing of HVAC systems in pharmaceutical industries worldwide.

Dr Jean-Denis Mallet
Pharmaplan, France
He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). Now he is member of the ECA advisory board and works for NNE Pharmaplan.

Andreas Nuhn
D&B Pharmadesign, Germany
Andreas Nuhn holds a diploma in process technology and works since 2019 as Managing Director and Shareholder for an engineering company for the pharmaceutical industry. He supports companies in GMP issues like preparation for authority audits but also in design and engineering of clean rooms and qualification. Additionally, he has specific experience in sterile processing.

Luigi Scaffidi
Boehringer Ingelheim Pharma, Germany
Luigi Scaffidi is working for Boehringer Ingelheim since 1986 in the areas of research, development and production. Since 2012 he is Manager Qualification / Validation / Aseptic / Hygiene in the Aseptic Quality Assurance with focus on aseptic, hygiene, qualification, validation.

Ruben van der Galiën
GE HealthCare, Netherlands
Ruben van der Galiën has been working as pharmacist in hospital, public and industrial pharmacies for four years. Since 2019 he is working for GE Healthcare Qualified Person / QA specialist. He has published several scientific papers including pharmacokinetics/pharmacodynamics of HIV and tuberculosis drugs and the setup of a CCS.

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	19 March 2024	20 March 2024
Non-Sterile Products – Challenges in Manufacturing & Quality	✓	n.a.
GMP – Green or Good Manufacturing Practice?	✓	n.a.
Packaging/Packaging Materials – Challenges & Solutions	n.a.	✓
European Aseptic Conference – Technology	✓	✓
Trends in Barrier Systems & Robotics	✓	✓
Modern Cleanroom Technology	✓	✓
Digitalisation & Artificial Intelligence	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Lyophilization – Modern Techniques & New Requirements	✓	✓
ATMPs – Hurdles & Achievements in Quality and Safety	✓	✓
Vaccines – Advantages & Challenges in Manufacturing	✓	✓
GMP PharmaTechnica Expo	✓	✓

Keynote on 19 March 2024

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	High pressure cleaning in pharmaceutical production. Advantages, challenges, sustainability and savings
MBV	B 20	TBN
Emerson Automation Solutions	B 22	TBN
Atec Steritec	B 28	Safe & Sterile Transfer with Minimal Operator Intervention
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	Annex 1's "Specific Risks Associated with Single-Use Systems"
Particle Measuring Systems	C 7	Facility Monitoring Systems
Yokogawa	C 9	Flow Imaging using FlowCam for High Performance Products to warrant constant excellent Quality

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Registration Form:
(06221) 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

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, both days for € 1,380.- 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. The fee is payable in advance after receipt of invoice.

Only until 31 December 2023: Save up to € 200 Early Bird Discount

Venue

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

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms close to the CongressCenter. You will receive a room reservation form when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone: +49 (0) 62 21 / 84 44-0 | Fax: +49 (0) 62 21 / 84 44 34
info@concept-heidelberg.de | www.concept-heidelberg.de

For questions regarding content please contact:
Dr Robert Eicher (Operations Director) at
+49 (0) 62 21 / 84 44 12, or at eicher@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49 (0) 62 21 / 84 44 51, or at strohwald@concept-heidelberg.de

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GERMANY

Reservation Form (Please complete in full)

Modern Cleanroom Technology

Part of PharmaCongress 2024

19/20 March 2024, Wiesbaden, Germany

☐ Day 1 & 2 (19/20 March 2024)
☐ Day 1 (19 March 2024)
☐ Day 2 (20 March 2024)

☐ Yes, I would also like to take part in the Social Event on the evening of 19 March 2024.

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1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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