



Speakers



Nikolaus Ferstl
University Hospital of Regensburg



Dr Lars Kreye
Boehringer Ingelheim



André Lourenco
NNE



Dr Jean Denis Mallet
Former Head of the French Pharma-
ceutical Inspection Dpt. AFSSAPS



Andreas Nuhn
Principal Consultant
GMP-Compliance

Clean Rooms & HVAC Systems

17/18 May 2022 | Vienna, Austria



Image: LEONHARD WEISS Fußbodentechnik GmbH & Co. KG

Highlights

- GMP-Guidance for Clean Rooms and HVAC Systems
- Zone concepts for sterile, non-sterile and highly potent products
- HVAC components and concepts
- GMP-compliant clean room walls, ceilings and floor
- Implementation of barrier systems (Isolator/RABS)
- Qualification of rooms and HVAC systems
- Classification & particle measurements according to ISO 14644
- Operation of clean rooms and barrier systems
 - Requalification
 - Monitoring & Trending
 - Maintenance

GMP requirements for planning,
qualification & operation

Objective

This course **outlines** the principles of planning, qualification and operation of cleanrooms & barrier systems and their associated HVAC systems in the GMP environment. Both the protection concepts and the premises for **aseptic** and **non-sterile** manufacturing will be addressed.

Background

Knowing the **regulatory requirements** on rooms and HVAC systems is an absolute prerequisite for all further steps like design, qualification and operation of clean rooms.

It is therefore essential to be aware of all restrictions and relations between material and personnel flows before starting with the building of clean rooms for pharmaceutical manufacturing. This is the starting point for the **zone concepts and the required airlocks**.

The clean room 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?

The **classification and qualification of the rooms** have to be done after the construction. The formal requirements on qualification are the same for clean rooms dedicated to the manufacture of both sterile and non-sterile dosage forms. Only the contents to be examined and fulfilled are different.

Qualification – which serves the verification of the correct functioning of the production rooms – merges into the **routine monitoring**. Moreover, the systems in place for requalification, change control, deviation and maintenance ensure the GMP status to be kept.

Target Audience

This course is directed at staff in pharmaceutical engineering departments and production, involved in the planning, qualification or operation of clean rooms.

Engineering companies and GMP-planners are also the target group of this course

Moderator

Andreas Nuhn

Social Event



On 17 May you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Programme

GMP-requirements for clean rooms and HVAC systems in the pharmaceutical industry

- The EU GMP guide, Annex 1 and 15, ISO Norms and other GMP relevant guidelines
- Definition of cleanliness: particles and microbiological limits
- Comparison of EU und US requirements
- Requirements during planning, construction and operation
- Experiences from inspections

Zone Concepts

- Considering of the frame conditions: premises, number of floors, products, technologies
- Estimation of the required spaces (with regards to the equipment and production capacities)
- Requirements according to the different clean room zones
- How to develop material and personal flows: from process to layout
- Planning with the technical room book
- Specific pressures cascades and airlock requirements
- Examples for zone concepts for sterile and non-sterile manufacturing including highly potent compounds

HVAC systems: from planning to commissioning

- Background for HVAC-Systems
- Design criteria
- GMP criteria and requirements for recovery time, air changes, air velocity, differential pressures, ...
- Usage of flow visualisation tools
- The different concepts possible from 100% fresh air to recirculation
- Different production types and the influence on HVAC systems and their GMP relevance
- Filters
- Control strategies
- Energy aspects
- Requirements for the construction site
- Monitoring systems

GMP requirements for clean rooms walls, ceilings and floors

- Description of requirements coming from planning, ISO norms and GMP guidelines
- Overview of the different wall and ceiling systems used in the pharmaceutical industry
- Components of wall systems: terminals, doors and windows
- The GMP-compliant clean room drain
- Floors: Slip-resistance vs. GMP
- Requirements for silicone joints (and coves)
- Assignment of the different systems to the different clean room classes – which walls, ceilings and floors are appropriate/allowed for which cleanliness class?
- Specifying the intended quality: the URS
- How to determine the specified quality of walls, ceilings and floors

Barrier Systems

- Definition of Isolator & RABS Systems
- Pros & Cons of the different systems
- Prerequisites for the usage of isolator/RABS
- Technical implementation of a barrier system

Particle testing and the ISO 14644

- Leak testing of filters
- Measuring over and under pressure
- Determination of the number of air changes
- Measurement of the recovery time
- Particle measurement and classification of the room
- Requirements for particle counters
- Number of measuring points and volumes according to ISO
- Air flow study, smoke study (UDF)
- Documentation of results

Qualification of clean room & HVAC System

- Definitions: classification, qualification, requalification, monitoring and recurring tests
- Organisation of the qualification of rooms and HVAC systems
- Usage and example of a risk analysis
- Steps taken in URS, DQ, IQ, OQ, and PQ
- Tests in the different qualification stages
- Typical problems in clean room and HVAC systems qualification
- Periodic requalification – which tests are really necessary?

Operation of clean rooms / barrier systems

- Recurring particle measurements
- Routine microbiological monitoring
- Tests for isolators
- What to do for maintenance?
- Cleaning
- Requalification
- Trending of data, evaluation, the PQR

Speakers



Nikolaus Ferstl
University Hospital of Regensburg

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 Senior Project Manager and as deputy head of the subsidiary of M&W in Vienna. In 2009 he changed from the planning to the user's side as technical director of the university hospital of Regensburg.



Dr Lars Kreye
Boehringer Ingelheim Pharma GmbH & Co. KG

Dr Kreye joined Boehringer Ingelheim as Head of Regulatory Compliance. Currently he is managing two aseptic filling lines (conventional clean room, vial filling), and one isolator line, as well as a packaging unit for final packaging.



André Lourenco
NNE

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
Former head of the French Inspection
Department AFSSAPS, Pharmaplan

Jean-Denis Mallet is a pharmacist. He was previously the Head of the Pharmaceutical Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). He also used to work in or with the pharmaceutical industry at various positions including QA, Production, and Engineering. Now he works for Pharmaplan.



Andreas Nuhn
Principal Consultant GMP Compliance

Andreas Nuhn holds a diploma in process technology and works as self-employed GMP Consultant since 2013 after almost 15 years in engineering companies in different jobs. He supports companies in general and specific GMP issues like preparation for authority audits but also in design and engineering of clean rooms.



Participants' comments from the June 2018 course:

„Presentations were well done. Presenters were very knowledgeable & were able to answer all questions very satisfactorily.“

Elidio Gil, Novo Nordisk Pharmaceutical Industries, USA

„Really fantastic course! I gained a lot of useful knowledge. There were great presenters and I feel confident in the information that they provided.“

Kristian Morton, Novo Nordisk Pharmaceutical Industries, USA

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

Clean Rooms & HVAC Systems, 17/18 May 2022, Vienna, Austria

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

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General terms and conditions

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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 2 weeks prior to the conference 10 %
 - Cancellation until 1 week prior to the conference 50 %
 - Cancellation within 1 week prior to the conference 100 %
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Date

Tuesday, 17 May 2022, 10.00 to approx. 18.15 h
(Registration and coffee 09.30 – 10.00 h)
Wednesday, 18 May 2022, 08.30 to approx. 15.45 h

Venue

Radisson Blu
Park Royal Palace Hotel, Vienna
Schlossallee 8
1140 Wien
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On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on site event, it will be conducted live online. In this case, you will be informed in due time.

Fees (per delegate, plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

The conference fee is payable in advance after receipt of invoice and includes dinner on the first day and lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. 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 one week 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.
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