

## Speakers



Nikolaus Ferstl  
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Dr Lars Kreye  
Boehringer Ingelheim, Germany



André Lourenco  
NNE, Denmark



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



Andreas Nuhn  
D&B Pharmadesign, Germany

# Clean Rooms & HVAC Systems



Live Online Training on 23/24 May 2023



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 clean rooms & 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



Participants' comments on this 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

## Programme

### GMP-Requirements for Clean Rooms and HVAC Systems in the Pharmaceutical Industry

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- 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

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- 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 pressure cascades and airlock requirements
- Examples for zone concepts for sterile and non-sterile manufacturing including highly potent compounds

### HVAC Systems: from Planning to Commissioning

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- 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 Room Walls, Ceilings and Floor

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- 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

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- 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

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- 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

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- 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

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



### Your Benefit

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at [www.gmp-certification.org](http://www.gmp-certification.org)

## 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 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 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 & Clean room 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**  
D&B Pharmadesign

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.

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, Live Online Training on 23/24 May 2023

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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GERMANY

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ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

#### General terms and conditions

- If you cannot attend the conference you have two options:
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 weeks prior to the conference 50 %
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cellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.

In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed). (As of January 2012).

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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](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.



## Date Live Online Training

Tuesday, 23 May 2023,  
09.00 to approx. 17.45 h CEST  
Wednesday, 24 May 2023,  
09.00 to approx. 16.30 h CEST

## Technical Requirements

We use Webex Events for our live online training courses and webinars. At [www.gmp-compliance.org/training/online-training-technical-information](http://www.gmp-compliance.org/training/online-training-technical-information) you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

## 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.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## Presentations/Certificate

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

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