ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers

Nikolaus Ferstl
Facility Engineering Services, Germany

Dr Lars Kreye
Boehringer Ingelheim, Germany

André Lourenco
NNE, Denmark

Dr Jean Denis Mallet
Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS, France

Andreas Nuhn
D&B Pharmadesign, Germany

Clean Rooms & HVAC Systems

Live Online Training on 13/14 May 2025

Image: LEONHARD WEISS Fußbodentechnik GmbH & Co. KG

Highlights

- GMP-Guidance for Clean Rooms and HVAC Systems
- Implementation of the Clean Room Requirements of EU GMP Annex 1
- 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 & Monitoring according to ISO 14644

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.

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

- 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 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

- 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

- 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?

Case Study Boehringer Ingelheim: Implementation of the Clean Room Requirements of EU GMP Annex 1

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

Speakers

Nikolaus Ferstl
Facility Engineering Services

Nikolaus Ferstl has been working for M&W (former LSMW), for example as Senior Project Manager and as deputy head of the subsidiary in Vienna. From 2009 to 2024, he was Technical Director of the University Hospital Regensburg and a freelance consultant for building and cleanroom technology. Today, he is Managing Director of the Facility Engineering Services GmbH.

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:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Clean Rooms & HVAC Systems, Live Online Training on 13/14 May 2025

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | 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 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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation 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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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 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, 13 May 2025,
09.00 to approx. 17.45 h CEST
Wednesday, 14 May 2025,
09.00 to approx. 16.30 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21616. To avoid incorrect information, please give us the exact address and full name of the participant.

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
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 per e-mail at
eicher@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at
schopka@concept-heidelberg.de