Clean Rooms & HVAC Systems
GMP requirements for planning, qualification & operation

SPEAKERS:

Dr Lars Kreye
Boehringer Ingelheim

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NNE

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ECA & Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS

Andreas Nuhn
Principal Consultant GMP-Compliance

Jørgen Pedersen
Formerly NNE

7-8 May 2019, Vienna, Austria

LEARNING GOALS:

- 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 floors
- 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

This education course is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager“. Please find details at www.gmp-certification.eu
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Objectives

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 Group

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.

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?

Moderator

Andreas Nuhn
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

Social Event
In the evening of the first course day, 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.

Speakers

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

Dr Jean-Denis Mallet,
ECA, former head of the French Inspection Department AFSSAPS, NNE 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 is member of the ECA advisory board and works for NNE 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.

Jørgen Pedersen,
NNE A/S
Jørgen has a M.Sc. in Building Engineering and has 40 years of experience in engineering and design of HVAC and utility systems. He has completed more than 35 pharmaceutical, biotech, bio-containment and laboratory projects. Jørgen had a position as Senior Specialist at NNE until end of 2018. He has given various lectures on clean room technology, standards and guidelines and is author of various publications on clean room technology.
Reservation Form (Please complete in full)

Clean Rooms & HVAC Systems
7-8 May 2019, Vienna, Austria

[ ] Mr  [ ] Ms

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number

PO Number if applicable

Street/P.O. Box

City

Zip Code

Country

Phone

Fax

E-Mail (please fill in)

Date

Tuesday, 7 May 2019, 10.00 to approx. 18.15 h

(Registration and coffee 09.30 – 10.00 h)

Wednesday, 8 May 2019, 08.30 to approx. 15.45 h

Venue

Radisson Blu Hotel
Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria

Phone +43-1-891109200
info.parkroyalpalace.vienna@radissonblu.com

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 conference documentation, 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 event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax (please fill in)

E-Mail (please fill in)

Important: Please indicate your company’s VAT ID Number

PO Number if applicable

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

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 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 until 30 April 2019). German law shall apply. Court of jurisdiction is Heidelberg.

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For questions regarding content:
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