ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers

Fabian Foerster
Westfalen

Markus Multhauf
Senior Consultant GMP Engineering

Dr Andreas Schieweck
GMP Inspector, Germany

GMP-compliant Gases for Pharmaceutical Manufacturing

Live Online Training on 25/26 November 2025

Image: Westfalen AG

Highlights

- Compressed Air, Nitrogen & Pure Steam
- Specifications and GMP Requirements
- GMP-Aspects in the Design of Gas Systems
- Planning, Commissioning & Qualification of Gas Systems
- Quality and Production of Gases for Pharma-Manufacturing

Production, Testing & Distribution

Objective

The aim of the seminar is to provide practical information on the key GMP, quality and engineering aspects in the planning and operation of systems for gaseous media such as nitrogen, compressed air, steam, medical gases, etc.

Background

From a GMP perspective, far too little attention is often paid to the media – they 'just come out of the wall'. Media, especially gaseous media, are usually brought to the place of use in a hidden manner, sometimes even disregarding the zoning. However, this grey area is not limited to the technology, but also affects the responsibilities and procedures for maintenance, sampling, testing, certificate acceptance and approval. Practical experience has shown that questions repeatedly arise during the planning, qualification and operation of media systems that cannot be answered clearly. This can lead to drastic quality problems, which is why media technology has increasingly become the focus of inspections in recent years.

In this seminar, we want to provide answers to practical questions, such as

- What do the regulatory requirements for gaseous media actually look like?
- Where can I find a valid specification?
- What does a GMP-compliant design of media systems look like?
- Which technologies are state-of-the-art?
- What needs to be considered when building and commissioning media systems?
- How often do filters need to be checked or replaced?
- Which components need to be qualified?
- Which quality parameters of gases must be tested, which can be taken from the certificate?

Target Audience

The target group are employees from technology, production and quality assurance in pharmaceutical and active ingredient production who are entrusted with the planning, qualification and operation of systems for gaseous media.

Moderator

Markus Multhauf

Programme

Gases in the GMP Environment: Regulations, Guidelines & Inspection Practice

- Regulatory requirements in connection with media systems
- Quality and specifications (e.g. nitrogen, compressed air, steam)
- Risk priorities from an inspector's perspective
- Supplier audits

Design of Compressed Air, Nitrogen and Vacuum Systems

- Compressed air generation & distribution
- Design of quantities, nominal diameters, flow rate, pressure losses
- URS for compressed air
- Pitfalls regarding the 5µm particle requirement in ISO 8573
- Nitrogen applications and supply systems
- Design principles vacuum-systems

Planning of GMP Media Systems

- PID symbols for GMP-piping systems
- Special components:
  - Valves
  - Detachable connections
  - Filter
- Interface cleanroom

Quality and Production from the Perspective of a Gas Manufacturer

- Quality assurance for air separation units, filling stations, tank vehicles, storage containers, cylinders for gases
- Necessary and unnecessary tests for incoming goods inspection of supplied gases
- Frequency and procedure for checking the inside of containers (bottles and truck tanks) for corrosion and contamination
- Training and training certificates for manufacturers and tank-truck drivers of gases
- Special technical features and developments in distribution systems and points of use for cold compressed gases
- Innovations in the quality assurance of gases (information on planned changes to Pharm.Eur. e.g. for monitoring oil content in compressed air)
- Individual production of specialty gases / reference standards

Construction, Commissioning & Qualification

- Requirements for execution, documentation, material certificates
- Welding, Bending, pressed connections: When and why?
- Construction site: Storage, material and personnel flow, separation of stainless steel and black steel work
- Remark on excessive requirements regarding construction site safety (lessons learned)
- SAT / Avoidance of double testing (GEP versus GMP)
- Qualification strategies: CPP's, CQA's, IQ, OQ, PQ

Requirements for Pure Steam

- Difference Pure & Clean steam
- Natural circulation or falling film evaporator: technology and design
- Feed water degassing & Non-condensable gases
- Control for dryness and superheat
- Sampling for conductivity, TOC
- Example CAPA: Wet materials found in Autoclave after completion of cycle
- Remark: Room air humidification (with deionised water, black steam, clean or pure steam)

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

Fabian Foerster
Westfalen

Fabian Foerster is a chemist and works for Westfalen AG as a Research & Development officer accreditation, qualification and validation.

Markus Multhauf
Senior Consultant GMP-Engineering

Markus Multhauf studied process engineering. He worked for HOECHST and for plant construction companies like Waldner and Hager+Elsasser. At LSMW/M+W he was design engineer for utility systems and project manager for 9 years. Then he was Head of Engineering at Aeropharm (SANDOZ). Since 2013 he is a freelancing engineer for pharmaceutical technology.

Dr Andreas Schieweck
GMP Inspector, Germany

Dr Schieweck is an inspector at the Mecklenburg-Vorpommern Drug Monitoring and Testing Agency. He specialises in the areas of sterile, biological medicinal products and medical gases and is active in the relevant expert groups on medicinal products.

NEWS

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GMP-compliant Gases for Pharmaceutical Manufacturing
Live Online Training on 25/26 November 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)

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If you cannot attend the conference you have two options:
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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.

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Date Live Online Training

Tuesday, 25 November 2025,
10.00 to approx. 16.30 h CET
Wednesday, 26 November 2025,
10.00 to approx. 12.30 h CET

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 € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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 22093. 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:
Ms Nicole Bach (Organisation Manager) at
+49(0)62 21/84 44 22, or at
nicole.bach@concept-heidelberg.de