ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers

Nikolaus Ferstl
Facility Engineering Services

Dr Markus Keller
Fraunhofer Institute for Manufacturing Engineering and Automation (IPA)

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

Markus Multhauf
Senior Consultant GMP-Engineering

Dr Jan Rau
Dockweiler

Dr Ingrid Walther
Former Head of the Business Unit iv Drugs, Fresenius

GMPs for Equipment, Utilities and Facilities

Good Engineering Practice for Pharmaceutical Companies and Suppliers

3-5 June 2025 | Munich, Germany

Highlights

- Regulations in the Technical GMP Environment
- Understanding Risk Analyses
- GMP-compliant Equipment Design
- Requirements on Materials and Surfaces
- Zone Concepts
- GMP Requirements for Cleanrooms, HVAC and Barrier Systems
- Renovation of GMP-Facilities
- GMP-compliant Clean Media Systems
- Integrated Qualification and Commissioning
- Technical Change Control & Deviations
- Maintenance & Calibration

All participants receive ECA's Guide on GMP-Design of Equipment

Objective

This course explains how the requirements laid down in the GMP and FDA regulations can be put into **technological and engineering practice**. The whole lifecycle from the design, the qualification and the maintenance of equipment is covered. The **Annex 15** of the EU GMP Guide plays an important role here as well.

As a participant of this event, you will also receive the 115-page ECA Guide GMP Equipment Design for download. The document is divided into 13 chapters. In addition to an understanding of GMP-compliant equipment design, chapters 1-4 elaborate the pharmaceutical principles of risk analysis and documented evidence of a GMP-relevant issue. Chapters 5 to 13 provide guidance on specific aspects of equipment that may be used in the manufacture of medicinal products.

Background

Technical compliance is a wide field, especially when taking into account the ICH framework which covers the whole lifecycle of pharmaceutical manufacturing.

It does not only mean to comply with regulatory guidelines, but also with submissions and the technological state of the art, meaning ISO and other standards as well as accepted good practices in the pharmaceutical industry.

In this GMP course we want to focus on the main topics with regard to compliance in the technical environment:

Technical QA aspects
There are a number of quality assurance systems which are crucial for the technical units. Most important are changes and deviations (as they also can occur in technical environment) which have or might have a direct impact on the pharmaceutical material produced. And even more important is the validation system, where the qualification of equipment, utilities and facilities has to be part of.

GMP Facility & Re-Construction
Designing an appropriate layout belongs to this part as well as understanding what the GMP requirements for the cleanrooms and for the HVAC systems are, depending on the type of manufacture. Re-Construction during on-going manufacture is supreme discipline in this field.

GMP-compliant design of equipment
A GMP-compliant design of equipment is the basis for fulfilling the technical requirements. In this respect, engineering assumes a prominent role in ensuring the safety of medicinal products. In this context, the need for material certificates is often subject to discussion.

Validation / Qualification
Not only GMP regulations but also inspectors consider qualified equipment and validated processes as the prerequisites for producing pharmaceutical quality. The identification of the equipment that has to be qualified by means of a risk analysis is a crucial point. This field has now re-gained considerable attention as the regulations are changing: After FDA's new guide on validation (and process verification) also Annex 15 of the EU GMP Guide has been revised.

Routine Operation
Preventive maintenance in pharmaceutical production is an essential element of the Pharmaceutical Quality System. Systems for calibration & handling of repairs are of equal importance for maintaining the qualified state. That's why maintenance and calibration are parts of an efficient requalification system, besides the change control and deviation systems of course.

Target Audience

This course is directed at staff in pharmaceutical engineering departments, at technicians, engineers, planners as well as plant constructors and equipment suppliers who are involved in tasks related to engineering work in a cGMP environment.

Programme

QA Systems with Technical Relevance

Part 1:
Change Control, Technical Changes

- Regulatory Requirements
- Identification of „Changes" – What has to be handled under Change Control?
- CC-Workflow and pitfalls
- Change Management in Routine Operations vs. Project work
- Marketing Authorisation – Regulatory Affairs for Engineers

Part 2:
Deviations, CAPA & Malfunctions

- Deviations in the technical environment
- Documentation in logbook and higher-level systems
- Evaluation of technical deviations
- When does a deviation require CAPAs?
- Handling of alarms
- Correlation between changes, deviations, repairs and maintenance
- Examples

Risk Analysis

- Managing risks in the technical environment
- Project risks
- Equipment risks
- Product risks
- Risk management tools
- Examples

Integrated Commissioning & Qualification

- Old V-model and new approaches
- Project Steps & GMP regulations
- Quality Overview & Control for Project Work
- GEP, SME, CQA & CPP: Keys for Commissioning & Qualification – Process
- What to include in an URS – & what not
- PID, Layout, Component-list, FDS, SDS, HDS, Material Certificates
- Re-construction vs. Green Field Projects

GMP Zone Concepts (sterile/non-sterile/highly potent)

- Basic GMP requirements for materials & pharmaceuticals handling
- Physical requirements (areas) vs Dynamic requirements (HVAC)
- Finding the correct requirements depending on the manufacturing operation
- Defining an appropriate layout and air lock concept
- Defining personnel & material flows
- Product vs Personnel Protection
- Product Protection concepts, types of air flows
- Avoiding Cross Contamination: the EMA idea
- The future of barrier systems (Isolator and RABS)

GMP Class Requirements (HVAC and Barrier Systems)

- Some HVAC system concepts (e.g. fresh air / recirculated air)
- Understanding the main parameters (volumes, pressure, cleanliness, etc.)
- GMP Classification and ISO standards, and their interaction
- The basics of air filtration and flushing air circulation
- Particle testing depending on the cleanroom zone
- Microbiological monitoring in a cleanroom
- Requirements on construction of floors, ceilings and walls
- Classification, Qualification, Requalification of Cleanrooms

What does GMP-compliant Design mean?

- GMP-Design & -Risk: It depends on the product...
- Special cases / Parts / Procedures: Heat Exchanger, Sampling Valves, Power Supply Safety, Clean-Room-Screw, Thread lubrication
- Cleanability, Turbulent Flow & Surfaces / Biofilm
- Drawings: PID-Symbols & 3D-rule
- Pest Control during construction & maintenance
- Documentation GEP vs. "ALCOA-plus"
- IT-life-cycle for GMP-Equipment

Basic Aspects of Hygienic Design and Material Selection

- Risk-based approach for the selection of suitable materials
- Equipment-specific definition of the hygiene-critical area
- Open & closed equipment
- Construction aspects
  - Cleanability
  - Drainability
  - Pipe connections
  - Screw joints
  - Inner corners and angles

Process Contact Surfaces: Specifications and Surface Treatments

- Definitions of surface qualities
- Surface quality requirements
- Surface treatment methods
  - Mechanical treatment
  - Chemical methods
  - Electrochemical treatment

Requirements and Components for Hygienic Tubing Systems, Welding & Weld Examination

- Piping & Tubing standards
- Cleanability & Dead Legs
- Detachable Connections
- Welding Technology & Welding Quality Criteria

Requirements for the Process Environment: the Clean Room

- Clean Room standards and classes
- Selection and procurement – factors influencing the selection of components
- Wall and ceiling systems
  - Acceptance tests for wall and ceiling
  - Requirements for clean room doors
- Floor systems
  - Acceptance tests for floors
- Critical clean room interfaces
- Application of components for different cleanliness classes

Upgrading, Re-Construction and Renovation of Facilities

- Required as built documentation to start
- What to consider in re-construction projects?
- Upgrade of an HVAC System
- How to protect the ongoing manufacturing operations
  - Protection of products
  - Protection of equipment, rooms and HVAC
  - Flow concepts and control of external personnel
  - Access control, pest control, cleaning
  - Documentation of protective measures
- Examples from recent projects

GMP Utility Systems (Water / Steam / Gases)

- Generation: From Source Review to Purified Water, WFI, Pure Steam
- Components: working principles (Softener, EDI, RO, UF...)
- Storage and Distribution concepts
- Sanitisation principles
- Automation, Instrumentation, Trending
- Specification & Design for Compressed Air
- Safety for Nitrogen-Systems
- API contaminated waste water

Maintenance & Calibration

- Life-cycle model of pharmaceutical equipment
- How to set up and maintain a maintenance/calibration system
- Definition and control: frequencies, activities, tolerances, acceptance criteria, etc.
- Timing of activities
- Documentation & labeling
- Data integrity

Social Event

On June 3rd 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

Nikolaus Ferstl
Facility Engineering Services

Nikolaus Ferstl has a bachelor degree in mechanical engineering. He 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 Markus Keller
Fraunhofer Institute for Manufacturing Engineering and Automation (IPA)

Markus Keller is a biologist and project manager at the Fraunhofer Institute for Manufacturing Engineering and Automation (IPA), Department of Cleanroom and Microproduction. His area of expertise includes the qualification of plants with regard to their cleanroom suitability.

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 and Cosmetics Inspection Department at the French Health Products Regulatory Agency. He also used to work in or with the pharmaceutical industry at various positions including QA, Production Management and Engineering. He has also been auditor of the International Red Cross. Now he works for Pharmaplan.

Speakers

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 engineering at Aeropharm (SANDOZ/ Novartis). Since 2013 he is a freelancing engineer for pharmaceutical technology.

Dr Jan Rau
Dockweiler

Jan Rau has been working with high-purity tubing systems made of stainless steels for the pharmaceutical industries since 1998. He is Quality Manager at Dockweiler AG and works in research and development, with a focus on metallurgy and surface analyses. He is chair of the DIN NA 003-01-14 AA committee on tubes and components for the food, chemical and pharmaceutical industries and a member of the CEN/TC 459/SC 10/WG 11. He is chair of the ASME BPE Subcommittee on Metallic Materials (MM) and a member of the ASME BPE Standards Committee, the Executive Committee, and the Subcommittee on Surface Finish (SF).

Dr Ingrid Walther
Pharma Consulting Walther, Former Head of the Business Unit iv Drugs, Fresenius

Dr Walther joined Fresenius AG in 1986. She was employed in various positions and has long years of experience in the fields of research and development, quality assurance/quality control and the management of strategic projects. In 1997 she assumed a position as head of the Business Unit Validation and GMP Compliance at Pharmaplan GmbH. In a subsequent position at Pharmaplan, she became responsible for consulting projects and became COO. In 2007, she re-joined Fresenius, heading the business unit iv Drugs & Oncology. Since July 2009 she runs her own business as consultant.

Participants' comments:

"Knowledgeable speakers provided great content and views."
Simon Rice, Angstrom Technology Ltd, UK

"Fascinating lectures/lecturers and overall positive atmosphere."
Jussi Heikkilä, FläktGroup Finland Oy

"Great course!"
Peter Dalsgaard Mønsted,
Region Sjælland Sygehusapoteket, Denmark

"Very interesting course. Not too broad nor too specific. Good level of speakers / talks."
Dr Raf De Dier, Cilag AG, Switzerland

"It was a pleasure to be present in this conference."
Sergio Guerreiro, Iberfar, Industria Farmaceutica SA, Portugal

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Reservation Form (Please complete in full)

GMPs for Equipment, Utilities and Facilities, 3-5 June 2025, Munich, Germany

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.
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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 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
Tuesday, 3 June 2025, 09.00 to approx. 17.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 4 June 2025, 08.30 to approx. 17.15 h
Thursday, 5 June 2025, 08.30 to approx. 14.45 h

Venue
HYPERION Hotel München
Truderinger Straße 13
81677 München
E-Mail: hyperion.muenchen@h-hotels.com

Fees (per delegate, plus VAT)
ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1.245
The conference fee is payable in advance after receipt of invoice.

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 – or search and register directly at www.gmp-compliance.org under the number 21610.

Presentations/Certificate
The presentations for this event will be available for you to download and print 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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