

Speakers



Nikolaus Ferstl
Facility Engineering Services



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



Dr Markus Keller
Fraunhofer Institute for Manufac-
turing Engineering and Automation
(IPA)



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



Live Online Training from 9-11 April 2024



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

Good Engineering Practice for
Pharmaceutical Companies and Suppliers

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.

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 and Marketing Authorisations

- 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

Pipework and Fittings, Connections, Welding & Seam Control

- 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

Speakers



Nikolaus Ferstl
Facility Engineering Services

Nikolaus Ferstl studied mechanical engineering and carried out pharmaceutical projects worldwide for LSMW/M+W as project and branch manager in Vienna. From 2009 to 2024, he was Technical Director of the University Hospital Regensburg and a freelance consultant for building and clean-room technology. Today he is Managing Director of Facility Engineering Services GmbH.



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 (Afsaps=ANSM). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross and member of the ECA advisory board. Now he works for Pharmaplan.



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.



Markus Multhauf
Senior Consultant GMP-Engineering

Markus Multhauf studied process engineering (TH Karlsruhe). 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 nine years. Then he was head engineer at Aero-pharm (SANDOZ/Novartis). Since 2013 he is a freelancing engineer for pharmaceutical technology.



Dr Jan Rau
Dockweiler

Jan Rau has worked in the field of austenitic CrNi steel tube systems since 1998. He is responsible for Quality Management and research projects with major focus on metallurgy and surface analyses at Dockweiler. He is chair of the DIN committee NA 003-01-14 AA Tubes and Components for the Food, Chemical and Pharmaceutical Industry, chair of the ASME BPE subcommittee on Metallic.



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

Reservation Form (Please complete in full)



Live Online Training: GMPs for Equipment, Utilities and Facilities, 9-11 April 2024

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

D-69007 Heidelberg
 GERMANY

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Date of the Live Online Training

Tuesday, 9 April 2024,
 09.00 to approx. 17.00 h CEST

Wednesday, 10 April 2024,
 09.00 to approx. 16.45 h CEST

Thursday, 11 April 2024,
 09.00 to approx. 16.45 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 € 2,090
 APIC Members € 2,190
 Non-ECA Members € 2,290
 EU GMP Inspectorates € 1.145

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.

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 Maximilian Bauer (Organisation Manager) at
 +49(0)62 21/84 44 25, or at
bauer@concept-heidelberg.de