

Speakers



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



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Senior Consultant



Markus Moulthauf
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Stephan Reuter
Optima Pharma



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

GMPs for Equipment, Utilities and Facilities

21-23 April 2020, Berlin, Germany



Highlights

- GMP-compliant Equipment Design
- Requirements on Materials and Surfaces
- GMP requirements for Cleanrooms, HVAC and Barrier Systems
- Re-Construction and Renovation of Facilities
- GMP-compliant Water Systems
- Qualification, Re-Qualification and Commissioning
- Technical Change Control
- Maintenance & Calibration
- Auditing of Technical Suppliers
- Impact of the new GMP Thinking on engineering

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 **new 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 deviations systems of course. Finally, auditing the own technical suppliers is a recurring activity from the beginning of a project until the outsourcing of engineering activities later on.

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 Authorization - 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

Qualification, Re-Qualification & Commissioning

- What to write in a URS & what not
- Using risk analysis from kick-off to routine operation
- Handling impact and non-impact systems
- From URS to PQ: step by step
- How to ensure traceability?
- System Verification / Validation
- Re-Qualification: How to..? And how often?
- Examples

Materials and Surfaces

- Which materials can be used and for what purpose?
- Stainless steel, plastics, polymers,...
- How smooth have surfaces to be? Roughness and structures of cleanable surfaces
- What are the requirements on welding?
- Effects of corrosion, failures, and damage

GMP-compliant equipment design

- Open and closed systems
- Overview on important construction details for sterile and non-sterile applications
- Design of gaskets and problems with gaskets
- Allowed lubricants
- Valves
- Pumps
- Examples of GMP-compliant equipment

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 personal & material flows
- Product vs Personal 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 on a cleanroom
- Requirements on construction of floors, ceilings and walls
- Classification, Qualification, Requalification of Cleanrooms

Upgrading, re-construction and renovation of facilities

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

Qualification and Management of technical suppliers

- Contract management: Commercial- vs. Engineering- vs. GMP-issues
- Selection and auditing of suppliers with a risk based approach
- How much GMP must a supplier have?
- Review of suppliers and their performance
- How to audit a technical supplier?
- Examples of managing suppliers for equipment, technical services, ...

Pharmaceutical Water Systems

- Regulation basics
- Generation: Purified Water, WFI, Pure Steam
- Components: working principles and hazards (Softener, EDI, RO,...)
- Storage and Distribution concepts
- Sanitisation principles, avoidance of biofilms
- Automation, Instrumentation, Trending
- How to handle OOS in a water system

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

Impact of the new GMP Thinking on engineering

- Impact of the new Annex 15
- State of validation / qualification in the US
- Impact of ASTM E 2500 on European projects
- Changes coming from ICH Q 8-10
- How to comply with EU and US requirements in technical projects
- Practical examples

Speakers



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 (Afssaps=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. He has been member of the ECA advisory board and works now for Pharmaplan.



Gert Moelgaard
Past Chairman of ISPE, Senior Consultant,
Moelgaard Consulting

Gert Moelgaard has been Vice President for Innovation & Business Development in NNE Pharmaplan. He has been working in the pharmaceutical industry since 1982 and has experience from a number of major engineering, automation and validation projects within pharmaceutical manufacturing. He has made international contributions in international conferences on automation, process validation, PAT and manufacturing excellence and has contributed to several books and technical guidelines. Now he is working in his own consultancy business.



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 9 years. Then he was head engineering at Aeropharm (SANDOZ/Novartis). Since 2013 he is a freelancing engineer for pharmaceutical technology.



Stephan Reuter
Optima Pharma

Stephan Reuter has more than 20 years experience in the pharmaceutical industry. He started his career in plant engineering for puremedia systems on the supplier site. He changed to the consulting business and has been Head of Engineering at Chemengineering where he was responsible for many pharma projects. He also worked for B.Braun in the position of the Global Head of Project Management. Now he is again working in the field of plant engineering and construction as the managing director at OPTIMA pharma.

Reservation Form (Please complete in full)

GMPs for Equipment, Utilities and Facilities, 21-23 April 2020, Berlin, Germany

If the bill-to-address deviates from the specifications on the right, please fill out here:

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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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.
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- Cancellation until 1 week prior to the conference 50%.

- Cancellation within 1 week prior to the conference 100%.

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cancellation or non-appearance. If you cannot take part, you have to inform us

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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 January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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(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, 21 April 2020, 09.00 to approx. 17.50 h

(Registration and coffee 08.30 – 09.00 h)

Wednesday, 22 April 2020, 09.00 to approx. 17.45 h

Thursday, 23 April 2020, 08.30 to approx. 14.50 h

Venue

Steigenberger Hotel Berlin

Los-Angeles-Platz 1

10789 Berlin, Germany

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Email berlin@steigenberger.de

Fees (per delegate, plus VAT)

ECA Members € 1,790

APIC Members € 1,890

Non-ECA Members € 1,990

EU GMP Inspectorates € 995

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all three 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 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 message. Or you register online at www.gmp-compliance.org.

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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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.

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.



Participants' comments:

"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