The Technical Compliance Manager

Avoiding Non-Compliance in the technical area

3 - 5 June 2014, Berlin, Germany

SPEAKERS:

Dr Gerhard Hauser
European Hygienic Engineering and Design Group (EHEDG)

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

Gert Moelgaard
NNE Pharmaplan

Markus Rohde
CSL Behring

Wolfgang Rudloff
gmp-experts

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

LEARNING OBJECTIVES:

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

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 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. An outlook to the upcoming changes to the engineering regulations is also given.

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 technical compliance:

Background knowledge

There are a number of quality assurance systems which are crucial for the technical units. Furthermore, beside the fundamentals of pharmaceutical technology for the key operations like tableting and sterile filling, understanding the role of engineering in regulatory submissions facilitates daily work.

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), Annex 15 of the EU GMP Guide is now subject to revision.

Routine Operation and technical QA aspects:

Preventive maintenance in pharmaceutical production as well as the documentation of changes are essential elements of the Pharmaceutical Quality System. Systems for calibration & handling technical failures, which are checked frequently during inspections, are of equal importance for maintaining the qualified state. 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 manufacture, at technicians, engineers, planners and plant constructors who are involved in tasks related to engineering work in a cGMP environment.

Programme

Impact of Regulatory Requirements on engineering

- Important guidelines with technical content
- GMP compliant documentation in the technical environment
  - QA systems with technical relevance
  - Change Control
  - Deviation / CAPA
  - Training
- Classification of technical deviations
- Correlation of technical malfunctions with the CAPA system & batch release
- Documentation in logbook and higher-level systems

Dr Ingrid Walter

Qualification, Re-Qualification & Commissioning

- Using risk analysis from kick-of to routine operation
- Handling impact and no-impact systems
- From the URS to PQ: step by step
- System Verification
- Re-Qualification: how to..? And how often?
- Examples

Markus Rohde

Regulatory Affairs for Engineers

- Types of Submissions in EU and US
- Structure and Content of submissions
- Technical Details which should or should not be written in filings to authorities

Dr Ingrid Walter

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

Dr Gerhard Hauser
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

Dr Gerhard Hauser

Requirements for cleanrooms and HVAC systems for different dosage forms
- Cleanroom standards, cGMP Regulations, and their interaction
- Finding the correct requirements depending on the manufacturing operation
- Protection concepts, types of air flows
- Defining an appropriate layout and air lock concept
- Requirements on floor, ceiling and walls
- Some HVAC system concepts-comparison fresh air / recirculating air
- Particle testing depending on the cleanroom zone
- Qualification of Cleanrooms
- Re-Qualification of rooms and air-handling systems

Dr Jean-Denis Mallet

Upgrading, re-construction and renovation of facilities
- How to handle documentation gaps
- How to protect the ongoing manufacturing operations
  - Protection of products
  - Protection of equipment, rooms and HVAC
  - Personal flow and handling of external personal, Access control
  - Documentation of protective measures
- What to consider in re-construction projects?
- Examples from recent projects

Markus Rohde

Technical Change Control
- Definitions of change management
- Regulatory aspects
- How to maintain a change control system
- Link between maintenance, change control and deviations
- Classification of technical changes
- Examples

Dr Ingrid Walter

Qualification and Management of technical suppliers
- 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, equipment parts, technical services, ..

Markus Rohde

Pharmaceutical Water Systems: Production & Storage and Distribution
- Influence of raw water
- Schematic water generation: Aqua Purificata, WFI
- Components: working principles and hazards (Softening, EDI, RO, ...)
- Loop concepts
- What to measure and control (physical and chemophysical)
- Modern sanitisation concepts, avoidance of biofilms
- How to handle OOS in a water system

Wolfgang Rudloff

Fundamentals of pharmaceutical technology
- Manufacture of oral solid dosage forms
  - Fundamentals of Granulation
  - Compaction/Tableting
  - Critical Process Parameters (CPQs)
    (how machine parameters affect the efficacy of a tablet)
  - Equipment requirements
- Sterile and aseptic operations
  - Compounding & filling
  - Machine concepts
  - Filtering
  - Critical Process Parameters (CPQs)
  - 100% controls
  - Media Fills

Dr Jean-Denis Mallet

Maintenance & Calibration
- Maintenance/calibration in the life-cycle model of pharmaceutical equipment
- How to set up and maintain a maintenance/calibration system
- How to define frequencies, activities, tolerances, acceptance criteria, etc.
- Permanent conflict: maintenance/calibration or production
- Documentation & labeling
- Data integrity

Wolfgang Rudloff

Impact of the new GMP Thinking on engineering
- Revision of 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

Gert Moelgaard
Speakers

Dr Gerhard Hauser,
Formerly Technical University of Munich; Member of the EHEDG
Dr Hauser was senior engineer at the chair of mechanical and plant engineering of Munich Technical University. He was also a member of the German mirror body for the European machinery directive (standardisation of hygiene and cleaning requirements on machines used in the food industry), member of the European Hygienic Engineering and Design Group (EHEDG), Chairman of the subgroup ‘Design Principles’. Now he is still giving lectures on hygienic design at the University of Karlsruhe. He has recently published two books on Hygienic Design.

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

Gert Moelgaard,
NNE Pharmaplan
Gert Moelgaard is 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.

Markus Rohde,
CSL Behring GmbH
Markus Rohde works for CSL Behring in Marburg in the position of the Deputy Head of the department Quality Management Engineering and as group leader for the qualification of equipment and utilities as well as for validation of automated systems.

Wolfgang Rudloff,
GMP-Experts
Mechanical Engineer, legal expert in cleanroom technology and GMP-management, expert in Industrial Engineering, worked in technical and process lead positions within Warner Lambert (now Pfizer) in Freiburg. His qualification comprises lead auditor, head of construction management, process engineering, GMP consultancy. After the position as managing director of LSMW / Switzerland he became in 2001 managing director for PCS. Today, he is a freelance consultant specialised in technical GMP management, auditing and training.

Dr Ingrid Walther
Pharma Consulting Walther
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

On Tuesday, 3 June 2014 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.
Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0,
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Robert Eicher (Operations Director) at
+49-62 21 / 84 44 12, or per e-mail at
eicher@concept-heidelberg.de.

For questions regarding reservation, hotel,
organisation etc.:
Ms Jessica Stürmer (Organisation Manager) at
+49-62 21 / 84 44 43,
or per e-mail at stuermer@concept-heidelberg.de.

Conference Folder

You cannot take part in this event? Just order the documenta-
tion at the price of € 380.- + VAT + postage and
packing. You can use the registration form for this pur-
pose. Please note: In order to ensure that the documenta-
tion is complete, The conference folder will not be
available until 2 weeks after the event.

GMP Certification Programme

This seminar is recognised within the GMP Certification
Programme. By attending selected seminars, the partici-
pant can acquire an additional certificate. We offer the
following modules:

ECA Certified Validation Manager
ECA Certified QA Manager
ECA Certified API Production Manager
ECA Certified Quality Control Manager
ECA Certified Technical Operations Manager
ECA Certified Computer Validation Manager
ECA Certified Regulatory Affairs Manager
ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will
find a text explaining which seminars are recognised for
which certificates. Or you send an e-mail to info@gmp-
compliance.org or a fax to +49-6221- 84 44 64 with the
request for information about the GMP Certification Pro-
grame. We will then send you our brochure on the

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA
Foundation) is an independent professional organisation
chaired by a Scientific Advisory Board with members
from the pharmaceutical industry and regulatory authori-
ties. The ECA Foundation’s goal is to support to the Phar-
maceutical Industry and Regulators to promote the move
towards a harmonised set of GMP and regulatory guide-
lines by providing information and interpretation of new
or updated guidances. The ECA Academy offers profes-
sional basic and advanced education (training) pro-
grames. All services offered by the ECA Academy and
with regard to ECA Academy Memberships are solely
managed by Concept Heidelberg (a leading European
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Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences
or Courses you will automatically become a ECA Acad-
emy Individual Member for two years - free of charge.
More information about ECA Academy can be obtained
on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a
EUR 200,- discount on the regular par-
ticipation fee of any European Confer-
ce or Course presented by the ECA
Academy. In addition you will receive
the GMP Guideline Manager Software
with a large number of guidelines, e.g.
EC Directives, FDA Guidelines, ICH
Guidelines.

Lufthansa is Mobility Partner for all ECA Events

As an ECA course or conference attendee, you will re-
ceive up to 20% discounted travel fares (according to
availability). And as Lufthansa German Airlines offers a
comprehensive global route network linking major cities
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And this is how it works: Once you registered for a
course or conference you will receive a link together
with your registration confirmation. Opening that link
will take you to the Mobility Partner Program website
where you can enter a code in the “Access to Event Book-
ing” area you will also receive. This will take you into an
online booking platform* that will automatically calcu-
late the discount offered or provide you with an even
better offer if another promotional fare is available.

We look forward to welcoming at one of our next events
– and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner
Program website – other wise the booking platform window will not
open.
Reservation Form (Please complete in full)

The Technical Compliance Manager
3-5 June 2014, Berlin, Germany

Mr.  Ms.

Title, first name, surname

Company

Important: Please indicate your company’s VAT ID Number
Purchase Order No. if applicable

Department

Street/P.O. Box

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:

- until 2 weeks prior to the conference: 10%,
- until 1 week prior to the conference: 50%,
- within 1 week prior to the conference: 100%.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. They will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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(As of January 2012)

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 101764
69007 Heidelberg
Germany

+ 49 6221 84 44 34

@ e-mail: info@concept-heidelberg.de

Internet: www.gmp-compliance.org

Date

Conference language
The official conference language will be English.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you register. The special negotiated rate for the duration of your stay should be made directly with the hotel. Early reservation is recommended.

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.

Fees
ECA Members €1,790 per delegate plus VAT,
Non-ECA Members €1,990 per delegate plus VAT,
EU GMP Inspectors €995 per delegate plus VAT.

ECA Members €1,790 per delegate plus VAT,
APIC Members €1,890 per delegate plus VAT,
Non-ECA Members €1,990 per delegate plus VAT.

NH Berlin Mitte
Leipziger Strasse 106-111
10117 Berlin
Phone +49 30 20376-0
Fax +49 30 20376-600

Date
Tuesday, 3 June 2014, 9.00 to approx. 18.15 h
Wednesday, 4 June 2014, 8.30 to approx. 17.15 h
Thursday, 5 June 2014, 8.30 to approx. 15.45 h

Venue

Registration and coffee 8.30 – 9.00 h
(Registration and coffee 8.30 – 9.00 h)
(Date and times subject to change)

Venue