

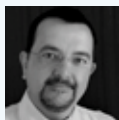
Speakers



Nikolaus Ferstl
University Hospital of Regensburg



Dr Johannes Krämer
CSL Behring



Markus Multhauf
Senior Consultant GMP-Engineering



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Merck

GMP-compliant Maintenance & Calibration



Live Online Training on 28/29 April 2021



Highlights

- GMP Requirements for Maintenance
- GMP Requirements for Calibration
- Risk-based Maintenance
- Development of a Maintenance Plan
- Handling Repairs and Replacements
- Documentation of Maintenance and Calibration
- Hygiene Aspects in Maintenance
- Maintenance Case Studies
 - Water System
 - HVAC System
 - Manufacturing Equipment
- „Maintenance 4.0“: Digital & Paperless

How to increase Compliance
and Plant Availability

Objective

This course's goal is to show how GMP requirements with regard to maintenance and calibration can be met while also taking into account economical constraints. It will be highlighted what the different requirements in the GMP environment are compared to other industries. It will further be shown, what a maintenance system should look like and how operational maintenance should be conducted.

Background

No downtime and **no risk** to products or patients are the main deliverables, a maintenance & calibration system should ensure. BUT it is also well known that the maintenance budget is among the first to be cut when cost-saving measures are being implemented. But still, a working maintenance system is a clearly **written requirement** in the pharmaceutical industry as well as in connected industries. See 21 CFR § 211.58 and 67, for example, as well as chapter 3 of the EU GMP Guide. Even as important as official requirements is the companies' own interest in having high plant availability and in **reducing the number of break downs**. The same is true for calibration: having manufactured medicinal products with equipment which has exceeded its calibration interval can lead to a recall of all manufactured batches from that time interval, **based on the criticality** of the measuring device. Reliable systems for Maintenance and Calibration must therefore be in place. Hygiene is another fundamental requirement in the pharmaceutical industry. It is an important aspect of maintenance work, that the equipment is set back to a cleaned operating state after maintenance or calibration, which has to be addressed in training and in the instructions for the maintenance work.

Another GMP specific aspect is the documentation of maintenance and calibration. Very specific requirements from traceability to the four eye or double-check principle exist and must be met. Calibration certificates not meeting GMP requirements are frequent inspection findings, especially when the calibration has been sourced out to a contractor.

In this course we will combine the understanding of the regulatory background and the design of a maintenance system as well as the training of practical aspects occurring in the daily maintenance work:

- What are GMP requirements with regard to Maintenance and Calibration?
- What can a maintenance system look like?
- How do I develop and write a maintenance plan?
- How should results be documented?
- How are time intervals for calibration and maintenance fixed?
- What must be done when acceptance criteria have not been met?

Examples will help to understand the basic requirements and how they can be fulfilled.

Target Audience

This course addresses the responsible persons for organising and carrying out maintenance and calibration in the plant as well as contractors carrying out maintenance and calibration.

Programme

Introduction and Regulatory Requirements

- Fundamentals and requirements for a maintenance concept
- GMP requirements & advice from guidelines and standards
- Planning maintenance during the qualification phase
- General objectives of maintenance, priorities
- Maintenance as part of the life cycle of manufacturing equipment
- Responsibilities: system owner / operator, technician, quality assurance, contractors

Development of a Maintenance System in the GMP Environment

- Definition of the maintenance strategy: proactive, reactive, predictive
- Service Levels, Increasing equipment availability, product safety
- System Impact (priority, importance, ranking)
- Inventory of equipment, HVAC, utilities
- Maintenance / service level matrix
- Controlling limits and ranges, strategy for setting limits
- Handling of repairs and replacements
- Determining spare part requirements
- Measuring maintenance performance, reports

A Risk-based Approach to Maintenance

- Internal versus external maintenance
- Are supplier's instructions for maintenance sufficient?
- Establishing maintenance items by risk analysis
- Determination of adequate materials to be used
- Evaluation of available GMP documentation to fix intervals
 - Deviations, CAPAs
 - Log-books
 - Maintenance documentation
- Cost savings

Organization of Maintenance

- Maintenance schedule, planned maintenance
- Execution of maintenance, flowcharts
- GMP-compliant documentation, paper based vs. electronic solutions
- GMP-Logbook, SOP's, Change Control
- Labeling and marking
- Staff organisation, qualification
- Workflow management
- Transfer of responsibilities
- Hazard and risk analysis

GMP-compliant Calibration

GMP-compliant calibration is a main aspect of maintenance within the pharmaceutical industry. Scope of this presentation is an introduction to the extensive requirements for instrument calibration. Beside a structured calibration system aspects of uncertainty and test equipment for calibration are presented. An example of executed calibration and its GMP-compliant documentation cover aspects of practical experience within this lecture.

- Structure of a GMP-compliant calibration system
- Traceability
- Requirements for measuring devices
- Uncertainty and how to avoid errors
- Execution of calibration - an example
- Calibration certificates and documentation
- Determination of calibration intervals

Hygiene Aspects in Maintenance Work

- Requirements for tools and auxiliary materials
- Typical weak points in maintenance work
- Sources of contamination:
 - Workmen
 - Tools and auxiliary devices
- Internal vs. external employees
- Logbooks, SOPs
- Restoring operational readiness
- Case study 1: Use of ladders in clean rooms
- Case study 2: Wipe mop, wash-machine, cleaning water
- Case study 3: Oil sealing for SS-surfaces in clean rooms

Case Study: Maintenance of a Pharmaceutical Water System

- Construction of water systems and components requiring maintenance
- Spare parts, intervals
- Special technical features for maintenance and repair
- Ozone + UV lamps
- Seals & Hoses
- Rouging
- 3.1 certification
- IT Security, Remote Maintenance & Life-Cycle
- Vibration analysis, thermography, ultrasonic analysis

Case Study: Maintenance of an HVAC System

- Fundamentals and requirements for an HVAC System
- Main parameter in a cleanroom
- Test procedures and measurement methods
- Execution of maintenance, checklists
- Case study, examples

Maintenance of Manufacturing Equipment: Examples

- Special requirements and tips & tricks
- Pumps
- Vessels
- Filling equipment

“Maintenance 4.0” – Digital & Paperless

- Case study CSL: implementation of a paperless maintenance system
- Usage of predictive maintenance tools
- Downtime reduction & cost savings

Speakers



Nikolaus Ferstl
University Hospital of Regensburg

Nikolaus Ferstl has a bachelor degree in mechanical engineering. He has almost 20 years of experience in the design of pharmaceutical facilities. He has been working for M&W (former LSMW), for example as Senior Project Manager and as deputy head of the subsidiary of M&W in Vienna. In 2009 he changed from the planning to the user's side as technical director of the university hospital of Regensburg.



Dr Johannes Krämer
CSL Behring GmbH

Dr Krämer studied energy- and process engineering. He has been Project-Engineer for Sanofi-Aventis for several years before he changed to Biopharmaceutical Operations at CSL Behring. He has been head of the department Plant Engineering and now he is head of Engineering at CSL Behring in Marburg.



Markus Multhauf
Senior Consultant GMP-Engineering

Markus Multhauf studied process engineering. He worked for Hoechst, Waldner, H+E and at LSMW / M+W (in the pharmaceutical infrastructure group and as project manager). At AEROPHARM (SANDOZ) he was technical manager. Since 2013 he is a freelance engineer in the field of GMP engineering.



Fritz Röder
Merck KGaA

Mr Röder is Senior QA Manager Qualification, Validation & Engineering at Merck KGaA in Darmstadt. He is a member of the expert group „Water“ of the EDQM. He has many years of experience in water treatment through his activities in plant engineering and pharmaceutical companies, including Bayer, Allergan and Merck.

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Live Online Training: GMP-compliant Maintenance & Calibration – 28/29 April 2021

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1. We are happy to welcome a substitute colleague at any time.

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- Cancellation within 1 week prior to the conference 100 %

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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 con-

ference (receipt of payment will not be confirmed!) (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Wednesday, 28 April 2021, 09.00 to approx. 17.45 h

Thursday, 29 April 2021, 09.00 to approx. 16.15 h

Times mentioned are CEST.

Technical Requirements

For our Live Online Events, we use Cisco WebEx, one of the leading suppliers of online meetings.

At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer 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 € 1,490

APIC Members € 1,590

Non-ECA Members € 1,690

EU GMP Inspectorates € 845

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.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at <https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars>.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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