



Includes Workshop  
"Development of a  
Maintenance Plan"

# GMP-compliant Maintenance & Calibration

9-10 October 2012, Prague, Czech Republic

## SPEAKERS:

Hartwig Hönerloh  
*Ferring*

Padraig Liggan  
*Amgen*

Wolfgang Rudloff  
*gmp-experts*

## LEARNING OBJECTIVES:

- GMP requirements on maintenance
- GMP requirements on calibration
- Maintenance in the life cycle of a plant
- Risk-based maintenance
- Development of a maintenance plan
- Documentation of calibration work
- Hygiene aspects in maintenance
- Preventive & predictive maintenance
- Case study of a maintenance system



# GMP-compliant Maintenance & Calibration

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## Objectives

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 further be shown, what a maintenance system should look like and how operational maintenance should be conducted.

## Background

It is 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 surrounding 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. Systems for Maintenance and Calibration must therefore be in place and they should be risk based, of course.

More practical is the fundamental requirement, that the maintenance work does not alter the quality of the product manufactured in the regarding plant. So, hygiene is also an important aspect of maintenance work which has to be addressed in training and in the instructions for the maintenance work.

Another problem occurring quite frequently is the documentation of maintenance and most of all calibration. Calibration certificates not meeting GMP requirements are frequent inspection findings, especially when the calibration has been sourced out to the contractor. Maintenance work in the pharmaceutical industry is **preventive**, of course, and is based on the above mentioned reasons. A new trend is **predictive maintenance**. Is it possible to avoid the yearly shut down by measuring key items to exactly find out the time when maintenance work has to be done.

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 intervals have not been kept?
- Is it possible to save money?
- Does predictive maintenance work?

## Target Audience

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

## Moderator

Wolfgang Rudloff

## Programme

### Introduction and regulatory requirements

- GMP requirements for maintenance
- Requirements & advice from guidelines and standards
- Maintenance during the life cycle of manufacturing equipment
- Increasing equipment availability
- Reproducibility of maintenance work

### 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

### Development of a maintenance system – maintenance in the life cycle of equipment

- Evolution of Maintenance and current thinking in industry
- Regulatory requirements for maintenance within the pharmaceutical industry
- Planning maintenance during the qualification phase
- Set up of maintenance system
- Determining spare part requirements
- Maintenance and spare parts change management
- Paper based vs. electronic solutions
- Maintenance - equipment life cycle considerations
- Measuring maintenance performance
- Industry case study

### Workshop: Development of a maintenance plan

- Structure of a maintenance plan
- Content of a maintenance plan
- Determination of inspection criteria
- Determination of acceptance criteria
- Usage of graphics, illustrations, photos

### Calibration in compliance with GMP requirements

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 test equipment
- Uncertainty and how to avoid errors
- Execution of calibration - an example
- Calibration certificates and documentation

### Hygiene aspects in maintenance work

- Weak points in pharmaceutical manufacturing equipment
- Typical weak points in maintenance work
- How to avoid and how to detect hygienic problems
- Sources of contamination:
  - Workmen
  - Tools and auxiliary devices

### Predictive maintenance

- Introduction to predictive maintenance techniques
- Predictive vs. preventive maintenance
- Setting up a predictive maintenance program
- Predictive maintenance in a regulated environment
- Potential pitfalls
- Financial benefits
- Industry case study

### Potential savings in maintenance

- Integration of maintenance costs in investment decisions
- Evaluation of down time, break down of production, repair costs
- Total cost of ownership consideration
- Internal versus external maintenance

### Social Event

On 9 October 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



**Hartwig Hönerloh**, *Ferring GmbH, Germany*

Hartwig Hönerloh serves in the business of Ferring GmbH Kiel since 01.04.2003. He is Associate Director of the group Technology Service and Validation since June 2006. Together with his team he is responsible amongst others for the calibration and qualification of process equipment and utilities at the Ferring GmbH site in Kiel, Germany.



**Padraig Liggan**, *Amgen Technology Ltd, Ireland*

Padraig Liggan is currently employed in a senior engineering role with Biotechnology company Amgen, currently he is involved in setting up equipment reliability, maintenance and process improvement programs in order to support large scale production of parenteral drug products. Padraig has a Masters degree (MEng) in Advanced Engineering and a degree BSc(H) in Computer Aided Manufacturing. He has also published a number of papers, including 'Maintenance and Facilities Outsourcing Excellence'; 'Lean Maintenance – A risk Based approach'; 'Applying Predictive Maintenance Techniques'.



**Wolfgang Rudloff**, *gmp-experts GmbH*

Mechanical Engineer, legal expert in cleanroom technology and GMP management, expert in industrial engineering, safety engineer, worked in technical and process lead positions within Warner Lamber-Gödecke 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, senior consultant and senior auditor for PCS. Today, he is a freelance consultant and specialises in technical GMP management, GMP consulting, auditing and training for the pharmaceutical and API industry.





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GMP-compliant Maintenance & Calibration

9-10 October 2012, Prague, Czech Republic

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Date

Tuesday, 9 October 2012, 09.00 to approx. 18.15 h  
(Registration and coffee 08.30 – 09.00 h )  
Wednesday, 10 October 2012, 08.30 to approx. 13.15

Venue

Corinthia Hotel Prague  
Kongresova 1  
14069 Praha 4, Czech Republic  
Phone + (0) 420 261 191 111  
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Fees

ECA Members € 1,490.- per delegate plus VAT  
APIC Members € 1,590.- per delegate plus VAT  
(does not include ECA membership)  
Non-ECA Members € 1,690.- per delegate plus VAT  
EU GMP Inspectors € 845.- per delegate plus VAT  
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on the first day 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 when you have registered for the event. Please use this form for your room reservation or be sure to mention “CON081012B” to receive the specially negotiated rate (single room € 137,50 per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 10 September 2012. 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](http://www.gmp-compliance.org).

Conference Language

The official conference language will be English.

Organisation and Contact

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