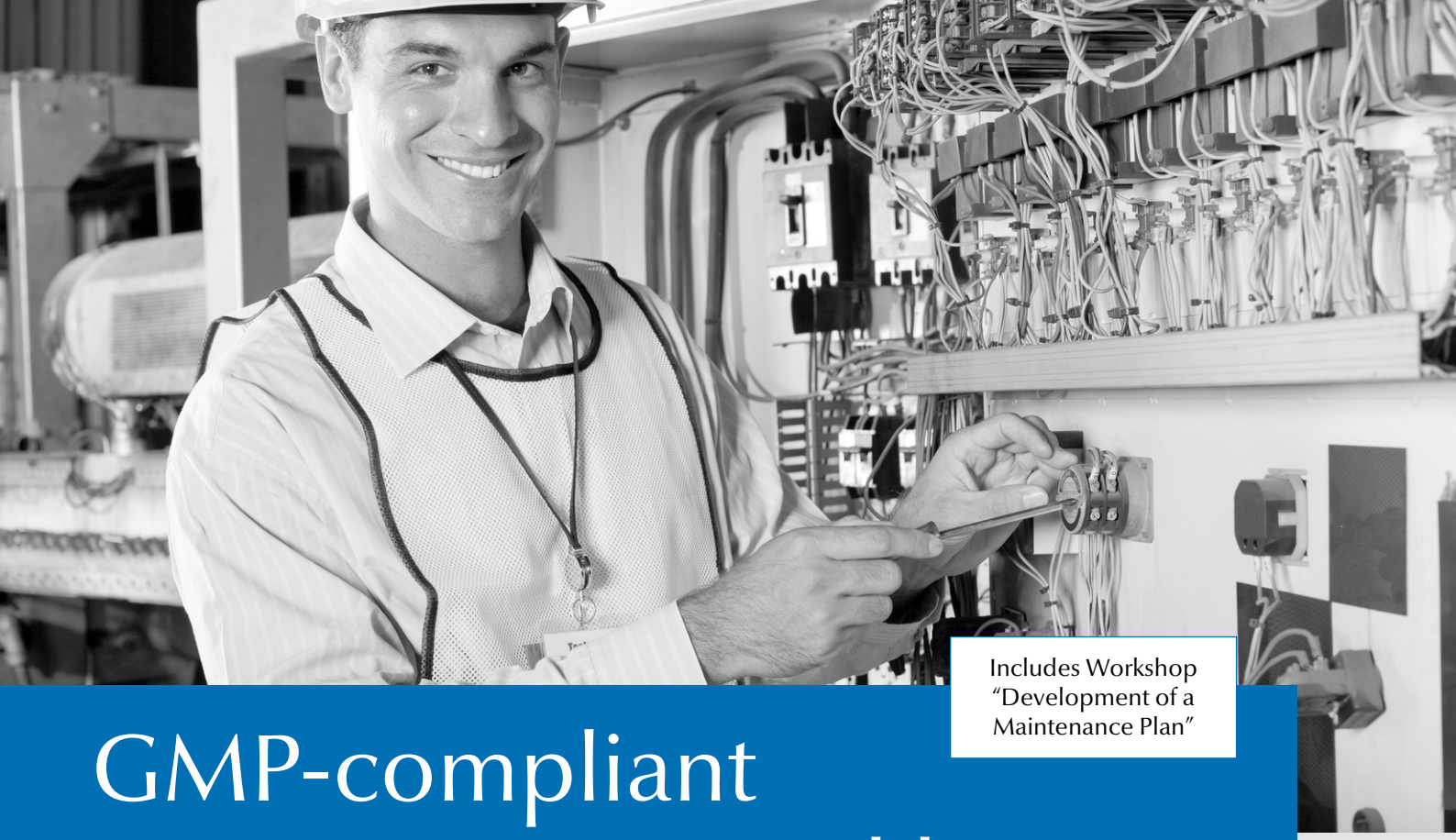


Includes Workshop "Development of a Maintenance Plan"

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

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager". Please find details at www.gmp-certification.eu

GMP-compliant Maintenance & Calibration

9-10 October 2012, Prague, Czech Republic

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

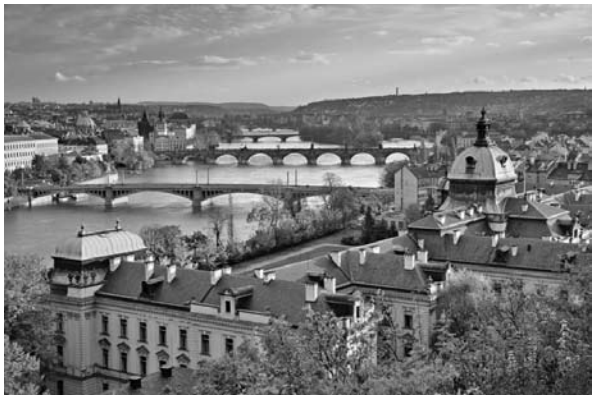
On 9 October you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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.



Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@gmp-compliance.org

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

GMP-compliant Maintenance & Calibration
9-10 October 2012, Prague, Czech Republic

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

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

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: Cancellation
- until 2 weeks prior to the conference 10 %
- until 1 weeks 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. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have 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)!

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
Fax +(0) 420 261 225 011

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 Inspectorates € 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.

Conference Language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone ++49-62 21/84 44-0
Fax ++49-62 21/84 44 34
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.:
Marion Grimm (Organisation Manager) at
+49-62 21 / 84 44 18, or per e-mail at
grimm@concept-heidelberg.de..

wa/vers/160820119