

Good Manufacturing Practices



GMP for Beginners – Understanding the importance of GMP

30 - 31 October 2014, Berlin, Germany

SPEAKERS:

Dr Bettina Pahlen
Quality x Pharma Consulting

Dr Heinrich Prinz
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LEARNING OBJECTIVES:

- GMP: Where do we come from – where do we go?
- Basic principles of GMP
 - Personnel
 - Hygiene
 - Premises / Production
 - Documentation
 - Risk management
 - Qualification / Validation
 - Communication with clients/ authorities
- Elements of a QA System
 - Change Control
 - Deviations
 - CAPA (Corrective Actions – Preventive Actions)
 - Failure Investigations
 - OOS (Out of Specification)
 - Audits – Inspections
 - Measurements against falsified products



GMP for Beginners

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Objectives

The course is designed for people who have no or little knowledge of GMP:

- You get to know the most important pharmaceutical regulations and their importance,
- you get a basic overview of GMP requirements in pharmaceutical production and
- you become familiar with technical terms from the field of GMP and their meaning

Background

In the manufacture and quality control of medicinal products, compliance with the GMP rules is the decisive aspect for manufacturing high-quality products. For this reason, every staff member in the pharmaceutical industry has to be familiar with the basic GMP requirements. The relevant European GMP regulations define the following prerequisites:

Commisson directive 2003/94/EC

The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the **concept of quality assurance and good manufacturing practice**

EudraLex Vol. 4 Good manufacturing practice (GMP) guidelines

2.9 Besides the basic training on the **theory and practice of Good Manufacturing Practice**, newly recruited personnel should receive training appropriate to the duties assigned to them.....

In practice, many members of staff are often unaware of the contents and meaning of the different GMP requirements from Europe and the US and their consequences for product quality. During this course, speakers with long-standing experience in the training of employees introduce and explain the most important elements of a pharmaceutical GMP system in an easy-to-understand way.

Target Group

The course is directed to staff from the pharmaceutical industry having no or little experience with the current GMP requirements. This includes both employees who, after their vocational training, enter the pharmaceutical industry and experienced colleagues who work for the first time in a GMP-regulated environment. Participation is also recommended for personnel from suppliers who have to understand the quality requirements of their customers.

Programme

GMP: where do we come from - where do we go to?

- Development of GMPs
- GMP: Goal and general ideas
- Types of regulatory documents and their meaning
- GMP regulation for APIs, medicinal products and excipients - a comparison
- Authorities and industry groups: ICH, PIC/S, EMA, FDA, WHO, APIC, ISPE, IPEC

GMP in the US

- Comparison of US and EU regulations
- Differences between European and FDA view on GMP / GMP vs cGMP
- Typical expectations of FDA and European inspectors

Quality Management System

- Quality Management System cited in the regulations
- General aspects of Quality Assurance
- How to implement and structure a system
- Responsibilities

Personnel and Training

- General aspects
- Qualification
- Key personnel
- Job descriptions
- Training (purpose, goals, contents, target groups)
- Planning and documentation of training

Hygiene / Personal Hygiene

- General aspects and rules
- Hygiene programme
- Personnel flow
- Medical examination
- Contamination
- Monitoring

Documentation

- Structure of documentation
- Responsibilities for the documentation
- SOP
- Documentation in the manufacturing process
- Documentation in the quality control
- Batch record review
- Annual report / Product quality report
- Specifications

Specific Aspects of a QA System

- Deviations
- CAPA
- Change Control
- OOS
- Failure Investigations
- Self-inspections

Risk Management

- Main topics of ICH Q 9 / Annex 20
- Risk management tools
- Use of risk analysis during qualification
- How to handle FMEA?

Premises / Production

- Requirements for room and equipment
- Classification of rooms
- Sterile production/isolator
- Maintenance of hygiene
- How to behave during production

Qualification/Calibration/Maintenance

- Definitions: Qualification, validation, calibration, maintenance, risk analysis
- Organizing qualification and validation: the validation master plan (VMP)
- Steps in qualification studies: DQ, IQ, OQ, PQ
- Qualification parameters of typical types of equipment: Clean rooms, water systems, production equipment, analytical equipment
- Performing risk analysis: tools and practical tips
- Calibration: critical types of equipment
- How to build up a calibration system
- Maintenance: Requirements and system
- Validation of computerised systems

Process Validation and Validation of Analytical Methods

- General aspects and requirements
- Process validation
- Documentation of process validation
- Validation of analytical methods
- Documentation of analytical methods validation

Cleaning Validation

- Regulators requirements
- The cleaning procedure
- Building up a cleaning validation
- Sampling
- Analytical tests

Audits and Inspections

- Types of audits
- Requirements
- Dos and don'ts for the auditee - How to survive audits?
- Performing audits and self-inspections
- Good audit practices

Packaging/Storage/Transportation

- Packaging/Storage/Transportation in the regulations
- Managing of packaging process
- What is necessary to regulate in a pharmaceutical company
- WHO good storage practice – elements and requirements
- Transportation as part of storage
- How to maintain the quality during transportation

Measurements against falsified Products

- Regulatory requirements
- Responsibilities of QP and the pharmaceutical industry
- What measurements can be taken
- Strategies against falsified products

Speakers



Dr Bettina Pahlen, *Quality x Pharma Consulting GmbH, Alling, Germany*

Bettina Pahlen, PhD, studied pharmacy at the University of Muenster, Germany, graduated in pharmaceutical chemistry and performed post-docs in USA and Germany. During the

last 15 years she worked at university, authority and in different areas of the pharmaceutical industry (R&D, manufacturing, quality control, quality assurance). Since July 2007, she has been working as a consultant in the pharmaceutical industry focussing on GxP Quality Assurance aspects.



Dr Heinrich Prinz, *Apceth, Germany*

Dr Prinz worked with Boehringer Mannheim before he joined Biotest where he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division. Since 2003 he works as a freelance

consultant and part of his time he is the Senior Supervisor 'Production and Quality Assurance' at Apceth, a biotech company.



Dr Wolfgang Schumacher, *F. Hoffmann-La Roche Ltd., Switzerland*

Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he is now Head

of the department of Quality Computer Systems. He is a member of the ECA Advisory Board

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.



Easy Registration



Reservation Form:
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69007 Heidelberg
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Reservation Form (Please complete in full)

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Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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1. We are happy to welcome a substitute colleague at any time.
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 - until 1 weeks prior to the conference 50 %
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Date

Thursday, 30 October 2014, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 31 October 2014, 08.30 h – 17.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
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Fees (per delegate plus VAT)

ECA Members € 1,290
APIC Members € 1,390
Non-ECA Members € 1,490
EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotels. You will receive a room reservation form when you have registered for the event. 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

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