GMP for Beginners –

Understanding the importance of GMP

15-16 November 2012, Prague, Czech Republic
18-19 April 2013, Barcelona, Spain

SPEAKERS:

Dr Bettina Pahlen
Quality x Pharma Consulting

Dr Heinrich Prinz
Apceth

Dr Hans-Peter Volkland
gmp-experts GmbH

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
  - Complaints, Recalls, Pharmacovigilance

ECA
EUROPEAN COMPLIANCE ACADEMY

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

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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

Complaints, Recalls, Pharmacovigilance
- Regulatory requirements
- Responsibilities of QP and QPPV
- How to handle complaints
- How to perform recalls
- Communication with authorities

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 Hans-Peter Volkland, *gmp-experts GmbH, Germany*
Dr Volkland studied Chemistry at the University of Constance and graduated in microbiology (ETH Zürich). He worked for several years in R&D and in various quality positions (QA, QC, Validation, Qualification). In 2001 he joined PCS (Pharmaceutical Consultancy Services) as Senior Consultant and Senior Auditor. In 2006 he set up his own consultancy company, Pharma and API Consulting (PAAC). In 2009 he founded GMP Experts which provides GMP consulting, auditing and training for the pharma and API business.

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

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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☐ 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 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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Date and Venue November 2012

Thursday, 15 November 2012, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 16 November 2012, 08.30 h – 17.00 h

Corinthia Hotel Prague
Kongresova 1
140 69, Prague 4, Czech Republic
Phone +420 261 191 111
Fax +420 261 225 011

Date and Venue April 2013

Thursday, 18 April 2013, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 19 April 2013, 08.30 h – 17.00 h

NH-Hotel Constanza
C/ Deu i Mata 69-99
28029 Barcelona, Spain
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Fees

ECA Members € 1,290.- per delegate plus VAT
APIC Members € 1,390.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,490.- per delegate plus VAT
EU GMP Inspectorates € 745.- per delegate plus VAT
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. Reservation should be made directly with the hotels not later than 15 February / 17 October 2012. 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 "XCON141112" (November 2012) resp. "ECA7655" (April 2013) to receive the specially negotiated rate (single room per night incl. breakfast: € 115,50 in November 2012, 143,- in April 2013) for the duration of your stay. 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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