Speakers

Ingo Ebeling
Abbott

Melanie Kinzner
Sandoz

Katja Kotter
Vetter Pharma-Fertigung

Sue Mann
Sue Mann Consultancy

Sebastian Rögner
Croma Pharma

The GMP-Compliance Manager

19/20 November 2024 | Hamburg, Germany

Highlights

- Current Regulatory Requirements and Expectations
- Deviations and CAPA
- Documentation Systems, Review and Approval
- Electronic Quality Management System Implementation (with a view on data Integrity)
- Risk Analysis
- Supplier Monitoring
- Quality Reviews

With 3 Workshops:
- Deviations and CAPA
- Quality Metrics and KPIs
- Risk-based Supplier Qualification

Objectives

During this Course you will learn how the various pharmaceutical quality and documentation systems work and how they interact. Experts from the pharmaceutical industry will show you possibilities to **improve your systems** and how to **run them efficiently and in compliance with (c)GMP**.

Background

Pharmaceutical Quality Assurance and GMP Compliance Managers are continuously facing new challenges due to changing regulatory requirements and at the same time increasing needs for efficiency.

In this context, QA and GMP-Compliance Managers must be familiar with many GMP-related aspects and systems like:

- Non-Conformance Management
- Quality Risk Management
- Document and Data Governance
- Monitoring and Quality Reports

And these are not stand-alone systems. They are all linked to each other: A **Deviation** causes a **Failure Investigation** which is followed by a **CAPA** that can lead to a Change and Change Control. All relevant information must be documented in **Quality Reviews** and **Risk Management** is the key to almost everything. And everything should be documented and data handled in an integer way.

Companies should have all these systems in place. Let's find out how we can get the most out of them!

Target Audience

This Course is designed for all persons in pharmaceutical, biopharmaceutical and API industry's production and quality units who establish, manage and improve quality and documentation systems.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg

Programme

Current Regulatory Developments and their Impact on the Quality Management System: Challenges and Opportunities

- New, revised and relevant GMP requirements for the Quality Management System

Deviation - Investigation – CAPA

- GMP requirements and expectations
- Deviation management: best industry practice
- Performing Failure Investigation
- Elements of investigations
- CAPA-System and elements
- Success factors for an integrated system
- Industry approaches for CAPA systems

Risk Analysis and Management

- The Principles of Risk Analysis
- A detailed look at FMEA and HACCP
- How to apply ICH Q9 "Quality Risk Management"
- Process improvement with Risk Analysis

Case Study: Implementation of an electronic Quality Management System (eQMS)

- Project overview
- Cost/benefit analysis
- Possibilities and limits of an eQMS
- Interfaces between the various quality systems
- Data Integrity: Background and points to consider
- Example: Change Control Process Flow in the eQMS

Documentation Systems and their Compliance with the Marketing Authorisation

- Regulatory requirements
- Document change management: Maintaining compliance
- Records retention
- Archiving
- How to keep track of raw data/GMP relevant documentation
- Language: local language vs. English; quality of translation
- Issue/training/effective date vs. new document version

How to Control the Flow of Documents

- Review and approval of Documents
- Batch Record Review process
- GMP process and data flow
- Documentation vs. Data integrity issues

Product Quality Review and Annual Product Review as Quality Enhancement Tools

- Best practices in combining the two reviews
- Statistical background and trending
- Timing of PQRs
- Responsibilities: who is responsible for generation of particular parts of the report, analysis and final conclusion
- Site specific versus product specific PQR
- Challenges and recommendations to overcome challenges
- Examples and case studies

Case Study: How to Monitor Suppliers

- Key Quality and Performance Indicators
- Reporting and Monitoring (trend analysis and targets)
- Who is involved – who is responsible?
- Outlook: the FDA Guidance on Quality Metrics

3 parallel Workshops:

1. Deviations - Failure Investigation - CAPA
2. Quality Metrics and KPIs: from Data Collection to Continuous Improvement
3. Risk Management in Supplier Qualification: How to reduce the effort of qualification without losing control and become non-compliant

You will be able to attend 2 of these workshops. Please choose the ones you like to attend when you register.

Social Event

On 19 November, you are cordially invited to a social event (city tour and dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Testimonials from last event:

"Enjoyed all presentations. It was like of a refresher training for me as I am in quality for 10 years. It was very interesting to hear from the speakers about their own experiences from the industry." Divya Sudhakaran, The Netherlands

Speakers

Ingo Ebeling
Abbott Laboratories

Ingo Ebeling is Head of MST (Technology Center) and Engineering department at the Abbott Laboratories production plant in Neustadt, Germany.

Melanie Kinzner
Sandoz International GmbH

Melanie Kinzner is Manager Due Diligence & External Collaboration.

Katja Kotter
Vetter Pharma-Fertigung GmbH & Co. KG

Katja Kotter is Vice President Regulatory Affairs/ Quality Compliance.

Sue Mann
Sue Mann Consultancy

Sue Mann is a Qualified Person and a QP Assessor in the U.K. working on behalf of the MHRA, representing the Royal Pharmaceutical Society. She was Vice President of International Quality Assurance at Shire Pharmaceuticals before founding her company in 2009.

Sebastian Rögner
Croma Pharma

Sebastian Rögner is Teamlead Validation Engineering and responsible for computerized system validation and software related data integrity aspects.

Your Benefit: Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires:
„... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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

Reservation Form (Please complete in full)

The GMP-Compliance Manager | 19/20 November 2024, Hamburg, Germany

Please choose TWO workshops:

☐ *Deviations - Failure Investigation - CAPA*
☐ *Quality Metrics and KPIs*
☐ *Risk Management in Supplier Qualification*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks 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)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Tuesday, 19 November 2024, 9.00 h – 17.30 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 20 November 2024, 08.30 h – 15.30 h

Venue

Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany
Phone: +49 (0) 40/ 22 63 62 0
E-Mail: hamburg@barcelo.com

Fees (per delegate, plus VAT)

ECA Members EUR 1.690€
APIC Members EUR 1.790€
Non-ECA Members EUR 1.890€
EU GMP Inspectorates EUR 945€
The conference fee is payable in advance after receipt of invoice and includes 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 hotel. You will receive a room reservation form/POG when you have registered for the course. 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.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64 | D-69007 Heidelberg
Phone: +49(0) 62 21/84 44-0 | Fax: 49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content:
Mr Wolfgang Schmitt (Operations Director) at
+49(0) 62 21/84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
+49(0) 62 21/84 44 22, or per e-mail at
nicole.bach@concept-heidelberg.de