Speakers

Ingo Ebeling
Abbott

Melanie Kinzner
Sandoz

Katja Kotter
Vetter Pharma-Fertigung

Veronika Kotzian
Croma Pharma

Sue Mann
Sue Mann Consultancy

The GMP-Compliance Manager

24/25 October 2023 | Berlin, 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

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

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 24 October, 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.

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.

Veronika Kotzian
Croma Pharma

Veronika Kotzian is Head of Quality Engineering. Before that she was – amongst others - Head of Unit Environmental Monitoring and a Quality Operations Manager at Boehringer Ingelheim (Austria).

Sue Mann
Sue Mann Consultancy, U.K.

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.

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:

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GERMANY

Reservation Form (Please complete in full)

The GMP-Compliance Manager | 24/25 October 2023, Berlin, 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)

Allgemeine Geschäftsbedingungen
Bei einer Stornierung der Teilnahme an der Veranstaltung berechnen wir folgende Bearbeitungsgebühr:
- Bis 4 Wochen vor Veranstaltungsbeginn 10% der Teilnahmegebühr.
- Bis 3 Wochen vor Veranstaltungsbeginn 25 % der Teilnahmegebühr.
- Bis 2 Wochen vor Veranstaltungsbeginn 50 % der Teilnahmegebühr.
- Innerhalb 2 Wochen vor Veranstaltungsbeginn 100 % der Teilnahmegebühr.

Selbstverständlich akzeptieren wir ohne zusätzliche Kosten einen Ersatzteilnehmer. Der Veranstalter behält sich Themen- sowie Referentenänderungen vor. Muss die Veranstaltung seitens des Veranstalters aus organisatorischen oder sonstigen Gründen abgesagt werden, wird die Teilnehmergebühr in voller Höhe erstattet.
Zahlungsbedingungen: Zahlbar ohne Abzug innerhalb von 10 Tagen nach Erhalt der Rechnung.

Bitte beachten Sie: Dies ist eine verbindliche Anmeldung. Stornierungen bedürfen der Schriftform. Die Stornogebühren richten sich nach dem Eingang der Stornierung. Im Falle des Nicht-Erscheinens auf der Veranstaltung ohne vorherige schriftliche Information werden die vollen Seminargebühren fällig. Die Teilnahmeberechtigung erfolgt nach Eingang der Zahlung. Der Zahlungseingang wird nicht bestätigt. (Stand Juli 2022)
Es gilt deutsches Recht. Gerichtsstand ist Heidelberg.

Datenschutz: Mit meiner Anmeldung erkläre ich mich einverstanden, dass Concept Heidelberg meine Daten für die Bearbeitung dieses Auftrages nutzt und mir dazu alle relevanten Informationen übersendet. Ausschließlich zu Informationen über diese und ähnlichen Leistungen wird mich Concept Heidelberg per Email und Post kontaktieren. Meine Daten werden nicht an Dritte weitergegeben (siehe auch Datenschutzbestimmungen unter http://www.gmp-navigator.com/nav_datenschutz.html). Ich kann jederzeit eine Änderung oder Löschung meiner gespeicherten Daten veranlassen.

Date

Tuesday, 24 October 2023, 9.00 h – 17.30 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 25 October 2023, 08.30 h – 15.30 h

Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
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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.

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For questions regarding reservation, hotel, organisation etc. please contact:
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