Speakers

Ingo Ebeling
Abbott

Melanie Kinzner
Sandoz

Katja Kotter
Vetter Pharma-Fertigung

Sue Mann
Sue Mann Consultancy

The GMP Compliance Manager

Live Online Training on 04/05 November 2020

Highlights

- Current Regulatory Requirements and Expectations
- Deviations and CAPA
- Data Integrity
- Documentation Systems, Review and Approval
- Risk Analysis
- Monitoring
- Quality Review

Objectives

During this Live Online Training 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 (on behalf of ECA)

Programme
Wednesday, 04 November 2020

Welcome and Introduction

Current Regulatory Developments and their Impact on the Quality Management System

- New and relevant EU GMP requirements for the Quality Management System
- Challenges and Opportunities

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

Q&A Session

Quality Metrics and KPIs

- From Data Collection to Continuous Improvement

Data Integrity: what the GMP Compliance Manager needs to know about it

- What's it all about (where does the hype come from)
- What you need to know about it
- What are inspectors looking for?

Risk Analysis - ICH Q9 and FMEA

- 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

Q&A Session

Programme
Thursday, 05 November 2020

Welcome and Introduction

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

Q&A Session

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

Q&A Session

Speakers

Ingo Ebeling
Abbott Laboratories

Ingo Ebeling is responsible for the MST (Manufacturing Science & Technology) and engineering department at the Abbott Laboratories production plant in Neustadt, Germany. Ingo has a history in QA, Business Excellence and logistics.

Melanie Kinzner
Sandoz International GmbH

Melanie Kinzner is Manager Due Diligence & External Collaboration. Before that she was Manager Global QA Development at Sandoz and Compliance Expert at Sanofi.

Katja Kotter
Vetter Pharma-Fertigung GmbH & Co. KG

Katja Kotter is Vice President Regulatory Affairs/ Quality Compliance.

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.

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Reservation Form (Please complete in full)

The GMP Compliance Manager
Live Online Training on 04/05 November 2020

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)

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Date of the Live Online Training
Wednesday, 04 November 2020, 9.00 h – 17.15 h
Thursday, 05 November 2020, 09.00 h – 15.30 h

Technical Requirements
For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)
ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Ordering a Recording
Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at any time at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact
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