



## Speakers



Ingo Ebeling  
Abbott



Melanie Kinzner  
Sandoz



Katja Kotter  
Vetter Pharma-Fertigung



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# The GMP Compliance Manager



Live Online Training on 03/04 November 2021



## 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

### 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

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- 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

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- From Data Collection to Continuous Improvement

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

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- 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

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- 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

### Documentation Systems and their Compliance with the Marketing Authorisation

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- 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.

### Your benefits:

### 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.

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### This Training Course is recognized for the GMP/GDP Certification Scheme"Certified Quality Assurance Manager



Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at [www.gmp-certification.org](http://www.gmp-certification.org)

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)



The GMP Compliance Manager  
Live Online Training on 03/04 November 2021

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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#### 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%.
- Cancellation until 1 week prior to the conference 50%.
- Cancellation within 1 week prior to the conference 100%.

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cellation 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 January 2012).

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 <https://www.gmp-compliance.org/privacy-policy>). 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 of the Live Online Training

Wednesday, 03 November 2021, 9.00 h – 17.15 h

Thursday, 04 November 2021, 09.00 h – 15.30 h

All times mentioned are CET.

## Technical Requirements

For our Live Online Training Courses and 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](http://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 order the recording of the Live Online Training at the earliest 10 days after the live performance at <https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars>.

## Organisation and Contact

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

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