

#### **SPEAKERS**

**INGO EBELING**  
Abbott Products

**MELANIE KINZNER**  
Sandoz International

**KATJA KOTTER**  
Vetter Pharma-Fertigung

**ANN MCGEE**  
McGee Pharma International

#### **With 3 Workshops:**

- Deviations and CAPA
- Integration of a Pharmaceutical Quality System
- Risk-based Supplier Qualification

# The GMP Compliance Manager

**18-19 November 2014**  
**Berlin, Germany**

#### **HIGHLIGHTS:**

- Regulatory Requirements and Expectations
- Pharmaceutical Quality Systems
  - Deviations and Failure Investigation
  - CAPA
  - Batch Record Review
  - Change Control
  - PQR / APR
  - Documentation Systems
  - Risk Analysis



# The GMP Compliance Manager

18-19 November 2014, Berlin, Germany

## 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, GMP Compliance Managers must be familiar with many GMP-related topics, such as:

- Knowledge and interpretation of Regulatory Requirements and Expectations
- Deviations and Failure Investigation
- CAPA
- Batch Record Review
- Change Control
- PQR / APR
- Documentation Systems
- Risk Analysis and Assessment

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 the **PQR** and **APR**. And everything should be integrated in a **Pharmaceutical Quality System**.

**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

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### Current Regulatory Developments and their Impact on Quality Assurance: Challenges and Opportunities

- ICH Q8 & Q9 – approach and implementation
- ICH Q10 - integration of the Quality Management System
- Chapter 1 of the EU-GMP Guide – implications of recent updates
- The Falsified Medicines Directive – new requirements for the Quality Management System

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

- Regulatory requirements on batch documentation
- 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

### Deviation and Failure Investigation

- cGMP Requirements/ Expectations
- Deviation management - Best industry practice
- Performing Failure Investigations – practical approaches (interdisciplinary teams, differential diagnose, visualisation, mind mapping)
- Recommendations for a good report
- Business Process Failure Investigation – What to define in the local procedure?

### CAPA System

- Philosophy and background
- cGMP requirements and expectations
- CAPA Subsystems
- Success factors for an integrated system
- Industry approaches for CAPA Systems

## Programme (cont'd)

### Batch Record Review

- Steps to consider for a successful BRR
- Responsibilities: manufacturer vs. supplier vs. contractor and QA vs. production vs. lab
- KPIs: examples and possible improvements to reduce review cycles times
- Deviations: how to handle during BRR/ transfer into CAPA system/ impact on batch release

### Change Control

- What is affected by Change Control?
- The process of Change Control
- Emergency changes
- Change Management in a global environment

### 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 with discussion around product groupings
- 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

### 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

### How the Systems are connected: the Vision of an integrated Pharma Quality System

System Integration of Batch Record Review, Deviation Management, CAPA, Change Control and PQR

### 3 parallel Workshops:

- 1) **Deviations - Failure Investigation - CAPA**
- 2) **Integration of a Pharmaceutical Quality System: What does it mean in practice?**
- 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.

## Speakers



**Ingo Ebeling**, *Abbott Products*

Ingo Ebeling is responsible for the Technology Center (Manufacturing Science & Technology) 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 Global QA Development. Before that she was Compliance Expert at Sanofi.



**Katja Kotter**, *Vetter Pharma-Fertigung GmbH & Co. KG*

Katja Kotter is Director Quality Assurance (Regulatory Affairs and Compliance).





**Ann McGee**, *McGee Pharma International, form. Senior Inspector of the Irish Medicines Board*


Ann McGee has extensive experience both in the pharmaceutical industry and as a regulator. She is a former Senior Inspector of the Irish Medicines Board, Chief Executive of the Pharmaceutical Society of Ireland and Deputy Chair of PIC/S. Ann McGee also has many years "hands-on" experience in industry.

## 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

### Date

Tuesday, 18 November 2014,  
9.00 h - 18.00 h  
(Registration and coffee 8.30 h - 9.00 h)  
Wednesday, 19 November 2014,  
08.30 h - 15.30 h

### Venue



InterCityHotel Berlin  
Hauptbahnhof  
Katharina-Paulus-Straße 5  
10557 Berlin, Germany  
Phone +49 (0)30 288 755 0  
Fax +49 (0)30 288 755 900

### Fees (per delegate plus VAT)

ECA Members € 1,490  
Non-ECA Members € 1,690  
APIC Members € 1,590  
EU GMP Inspectorates € 845  
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 hotel. You will receive a room reservation form with all further information when you have registered for the event. 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](http://www.gmp-compliance.org).

### Conference language

The official conference language will be English.

### 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, Germany  
Phone +49 (0) 62 21/84 44-0  
Fax +49 (0) 62 21/84 44 34  
E-mail: [info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

### For questions regarding content:

Mr Wolfgang Schmitt (Operations Director)  
at +49-(0)6221/84 44 39 or per e-mail  
at [w.schmitt@concept-heidelberg.de](mailto:w.schmitt@concept-heidelberg.de).

### For questions regarding reservation, hotel, organisation etc.:

Ms Nicole Bach (Organisation Manager)  
at +49-(0)62 21 / 84 44 22,  
or per e-mail at  
[bach@concept-heidelberg.de](mailto:bach@concept-heidelberg.de).



### Social Event

On 18 November, you are cordially invited to a social event in Berlin. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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

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CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
Fax +49 (0) 6221/84 44 34

69007 Heidelberg  
Germany

Reservation Form (Please complete in full)

 +49 6221 84 44 34

### The GMP Compliance Manager

18-19 November 2014, Berlin, Germany

Mr  Ms

Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**

**Purchase Order Number, if applicable**

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

Please choose TWO workshops:

- Deviations - Failure Investigation - CAPA
- Integration of a Pharmaceutical Quality System
- Risk Management in Supplier Qualification

### 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 %.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 January 2012).

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