ECA
ACADEMY

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

* This conference is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

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

Current Regulatory Developments and their Impact on Quality Assurance: Challenges and Opprtunities

- 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.

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
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.

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.

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

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

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The GMP Compliance Manager
18-19 November 2014, Berlin, Germany

☐ Mr ☐ Ms

Please choose TWO workshops:
☐ Deviations - Failure Investigation - CAPA
☐ Integration of a Pharmaceutical Quality System
☐ Risk Management in Supplier Qualification

Title, first name, surname

Company

Department

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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).

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 http://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.

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