ECA
European Compliance Academy

SPEAKERS

DR BERNHARD BÖHM
Boehringer Ingelheim

INGO EBELING
Abbott Products

DR DANIEL MARQUARDT
Boehringer Ingelheim

CLODAGH PHELAN
Ann McGee Consulting Ltd.

With 3 Workshops:
- Deviations and CAPA
- PQR/APR
- Risk Analysis

The GMP Compliance Manager

24-25 November 2011, Frankfurt/Main, Germany

HIGHLIGHTS:

- Regulatory Requirements and Expectations
- 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

24-25 November 2011, Frankfurt/Main, Germany

Objectives

During this Education Course you will learn how the various pharmaceutical quality and documentation systems work and how they interact. Experts from pharmaceutical industry will show you possibilities to **improve your systems** and how to **run them efficiently** and (c) GMP-compliant.

Background

Due to changing regulatory requirements and at the same time increasing needs for efficiency, pharmaceutical Quality Assurance and GMP Compliance Managers are continuously facing new challenges.

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

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**. And all relevant information must be documented in the **PQR** and **APR**.

Companies should have all these systems in place. Let's find out how we can get the most out of them!

Excerpt from an FDA Warning Letter:

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Complete, true and accurate records are the foundation for good GMPs. Reliable documentation is a control which raises assurance of the quality of the product manufactured. Violations concerning inadequate documentation are serious and should be handled as such.

Target Audience

This Education 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

- What regulations do require documentation
  - Systems, development, production
- What guidance do we have to structure and design documentation
- What purpose does the documentation serve
- What improvements can be considered
- How do we define responsibilities
- How do we identify risks in the documentation

Documentation Systems and their Compliance with the Marketing Authorisation

- Regulatory requirements on batch documentation
- Structure and creation of batch records
- Document change management: Maintaining compliance

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 local procedure?

CAPA System

Programme (cont'd)

- Philosophy and background
- cGMP Requirements/ expectations
- CAPA Subsystems
- Success factors for an integrated System
- Industry approaches for CAPA Systems

Batch Record Review

- Regulatory requirements
- Steps to consider for a successful BRR
- Checking the BR step by step
- How to perform the BRR?

Change Control

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

Product Quality Review vs. Annual Product Review

- Regulatory requirements on PQR and APR
- How to review, how to focus
- FDA Warning Letters on Annual Product Review
- Proposed Chapters of an Annual Product Review

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

3 parallel Workshops:

- Deviations - Failure Investigation - CAPA
- PQR/APR – Pooling the Information
- Risk Analysis and Management

You will be able to attend 2 of these workshops. Please choose the ones you like to attend when you register.

Speakers

Dr Bernhard Böhm, *Boehringer Ingelheim Pharma GmbH & Co. KG*
Dr Bernhard Böhm is Project Leader R&D at the Boehringer Ingelheim site in Biberach, Germany. In 1999, he started at Solvay Pharmaceuticals as the head of the Regulatory Compliance Group. After being responsible for a production department, he became the head of QA and Quality Commissioner (ISO 9000). From 2005 -2006 he was QA manager at Solvay´s French production site

Ingo Ebeling, *Abbott Products*
From 2001 to 2005, Ingo Ebeling was Head of Quality Assurance at the Solvay Pharmaceuticals production plant in Neustadt, Germany (now Abbott). Later he was also responsible for the logistic department with focus on production planning and purchasing activities. In January 2007 he became responsible for production compliance and was supporting process transfers and process optimisation. In October 2010 he became Plant Performance Manager being responsible for all operational excellence activities within the plant.

Dr Daniel Marquardt, *Boehringer Ingelheim Pharma GmbH & Co. KG*
After joining Boehringer Ingelheim in 2002 he has held different positions, i.e. Head of Process Quality Assurance Solids/ Qualified Person, Pharmaceutical Production Manager and Post Launch Manager of the German DPI Launch Facility, Director Supply Chain Management and Director Business Process Excellence. In this position he was responsible for the design and implementation of a lean transformational program at the German manufacturing pharma sites Ingelheim, Biberach and Dortmund. Since March 2011 he is amongst others responsible for Operation's Global Business Process Excellence initiative at Boehringer Ingelheim GmbH.

Clodagh Phelan, *Ann McGee Consulting Ltd.*
Clodagh Phelan is a senior consultant, having over 11 years industry experience across product lifecycles, including GCP, GLP, GMP and GDP. She has obtained vast experience in Quality Management Systems, Regulatory Compliance throughout her career. Most recently, Clodagh held the position of Senior Quality Assurance Director and Board Member at Shionogi Ireland. Other companies Clodagh Phelan has worked for are Sona, Pfizer, United Drug plc and Braun Medical.

Social Event

On 24November, you are cordially invited to a social event in Frankfurt. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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
Thursday, 24 November 2011, 9.00 h – 17.30 h
(Registration and coffee 8.30 h – 9.00 h)
Friday, 25 November 2011, 08.30 h – 15.30 h

Venue
Welcome Hotel Frankfurt
Leonardo-da-Vinci-Allee 2
60486 Frankfurt/Main, Germany
Phone +49 (0) 69 770 670 0
Fax +49 (0)69 770 670 444

Fees
ECA Members € 1,490.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
APIC Members € 1,590,- per delegate plus VAT (does not include ECA membership)
EU GMP Inspectorates € 845.- per delegate plus VAT
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 when you have registered for the conference. Please use this form for your room reservation or be sure to mention "6996 ECA Event" to receive the specially negotiated rate for the duration of your stay.

Reservation should be made directly with the hotel not later than 23 October 2011. 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
CONCEPT HEIDELBERG
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D-69007 Heidelberg, Germany
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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.

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Reservation Form (Please complete in full)

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The GMP Compliance Manager
24-25 November 2011, Frankfurt/Main, Germany
Please choose TWO workshops:
☐ Deviations - Failure Investigation - CAPA
☐ PQR/APR – Pooling the Information
☐ Risk Analysis and Management

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order Number, if applicable**

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E-Mail (Please fill in)

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)!

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