

## SPEAKERS

**DR BERNHARD BÖHM**  
Boehringer Ingelheim

**INGO EBELING**  
Abbott Products

**DR DANIEL MARQUARDT**  
Boehringer Ingelheim

**CLODAGH PHELAN**  
McGee Pharma International

### With 3 Workshops:

- Deviations and CAPA
- PQR/APR
- Risk-based Supplier Qualification

# The GMP Compliance Manager

**15 – 16 November 2012,  
Budapest, Hungary**

## HIGHLIGHTS:

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



# The GMP Compliance Manager

15 – 16 November 2012, Budapest, Hungary

## Objectives

During this Education 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**. 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:

### Excerpt from an FDA Warning Letter:

*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
- 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
- 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?

## Programme (cont'd)

### CAPA System

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

### 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 vs. Annual Product Review

- 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

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

### 3 parallel Workshops:

- 1) **Deviations - Failure Investigation - CAPA**
- 2) **How to improve your PQR/APR:** Examples and Case Studies
- 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

### **Dr Bernhard Böhm**, *Boehringer Ingelheim Pharma GmbH & Co. KG*

Dr Bernhard Böhm is Head of R&D Project Management Late Stage at the Boehringer Ingelheim site in Biberach, Germany. Before that he was Head of the Regulatory Compliance Group and later QA Manager at Solvay's French production site.

### **Ingo Ebeling**, *Abbott Products*

Ingo Ebeling is responsible for production compliance, process optimisation and analytical improvements. In former positions he was Head of Quality Assurance and Business Excellence Manager.

### **Dr Daniel Marquardt**, *Boehringer Ingelheim Pharma GmbH & Co. KG*

After joining Boehringer Ingelheim in 2002 he has held Daniel Marquardt is amongst others responsible for the Operation's Global Business Process Excellence Initiative at Boehringer Ingelheim GmbH. 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.


### **Clodagh Phelan**, *McGee Pharma International*


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 and Regulatory Compliance throughout her career. Most recently, Clodagh held the position of Senior Quality Assurance Director and Board Member at Shionogi Ireland.

## 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, 15 November 2012, 9.00 h – 17.30 h  
(Registration and coffee 8.30 h – 9.00 h)  
Friday, 16 November 2012, 08.30 h – 15.30 h

### Venue

Hilton Budapest WestEnd  
Váci út 1-3  
1062 Budapest, Hungary  
Phone +36 1 288 5500  
Fax +36 1 288 5588

### 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. Please make your reservation via the Personalised Online Group Page [www.budapest-westend.hilton.com/ECA1411](http://www.budapest-westend.hilton.com/ECA1411) where you also can modify/cancel your reservation until 3 October 2012 without any penalty (single room € 125,- per night incl. breakfast + 18% VAT + city tax). 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.

### Social Event

On 15 November, you are cordially invited to a social event in Budapest. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



### Organisation and Contact

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](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).

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

Reservation Form (Please complete in full)

 +49 6221 84 44 34

### The GMP Compliance Manager

15 – 16 November 2012, Budapest, Hungary

Mr  Ms

Please choose TWO workshops:

- Deviations - Failure Investigation - CAPA  
 How to improve your PQR/APR  
 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**

\_\_\_\_\_  
Street / P.O. Box

\_\_\_\_\_  
City

\_\_\_\_\_  
Zip Code

\_\_\_\_\_  
Country

\_\_\_\_\_  
Phone / Fax

\_\_\_\_\_  
E-Mail (Please fill in)

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

69007 Heidelberg  
Germany

### 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)!