

## 29 - 30 March 2011, Vienna, Austria

## **SPEAKERS:**

### Dr Bernhard Böhm

Boehringer Ingelheim

### **Ingo Ebeling**

Abbott Products

## Ann McGee,

Ann McGee Consulting Ltd., form. Senior Inspector of the Irish Medicines Board

## Dr Monika Schlapp

Boehringer Ingelheim



This course is supported by:



## **LEARNING OBJECTIVES:**

## ■ GMP Requirements

- Regulatory Requirements
- What do Authorities expect?
- Good Documentation Practice
- Efficient Deviation Management

## Process Improvement:

- How to structure Reviews
- Systems and Tools for Batch Record Evaluation
- The Use of Checklists
- Batch Record Review as part of the Batch Release

## Case Studies

- Electronic Batch Record
- How to reduce Review Time

## **Efficient Batch Record Review**

29 - 30 March 2011, Vienna, Austria

## **Learning Objectives**

During this course, you will learn all relevant aspects to conduct and to improve your system of the Batch Record Review. Furthermore, you will get to know possibilities and tools to **increase efficiency and decrease costs** at your company.

### **Background**

The Batch Record Review is an essential tool for assuring the quality of a pharmaceutical process.

Various regulations and guidelines address this topic for the pharmaceutical industry and it is a very important step before a product can be released by a Qualified Person. However, over the years, documentation has become more and more extensive and the review can be very time-consuming.

Furthermore, many observations made in inspections relate directly to the review of documents. This fact clearly demonstrates the importance and challenge of implementing a GMP/FDA-compliant Batch Record Review.

During this Education Course, experts from the pharmaceutical and API industry will cover all relevant aspects helping you to improve your batch record review. An optimised batch record review will also enable you to improve your process capabilities.

### **Target Group**

This Education Course is designed for all persons in Production and Quality Units who deal with the review of documentation in pharmaceutical, biopharmaceutical and API production. It is also addressed to Qualified Persons who want to improve their system of the batch record review.

#### Moderator

Daniel Scheidegger Chairman of the ECA

### **Programme**

### **Structure of Pharmaceutical Documentation**

- Review of recommendation and regulations
- Identifying the purpose of documents
- Discussion of possible structures
- Design of documentation

### **Batch Record Review as Part of the Quality System**

- What needs to be reviewed
- Regulatory requirements for review
- Batch record review for European GMP compliance
- Batch review as part of the release

# Case Study: Electronic Batch Record – a competitive Advantage?

- Transition paper based to EBR
- Master approval
- How efficient is a EBR system?
- Challenges in the introduction phase of EBR
- Electronic Batch Record Review by EBR

## Regulatory Requirements applying to Batch Record Review

- Basic regulations
- FDA requirements and recent warning letter
- ICH Q7A requirements

## How to handle the Documentation

- Master batch document design
- Creation/change of master documents
- Distribution
- Collection of records
- Archiving and retrieval
- Solutions for
  - Paper
  - Electronic systems
  - Hybrid systems

## Which Steps should be taken into Account in the Process for a successful Batch Record Review

- Preparation
- Line clearance
- Process steps
- Changes during the process
- Deviations in production
- Certificates of analysis

## Improve your Process Capability by Batch Record Review

- How to structure reviews
- Different assurance approaches in review
- Responsibilities for review

## Case Study: Operational Excellence Tools to reduce Batch Record Review Time

- History of Operational Excellence
- Tools and philosophy
- The project: batch record work stream reduction
- How to use Kaizen workshops

### **Efficiency in Batch Record Review**

- Layout and handling
- How to reduce review time: examples
- How to handle and document deviations
- How to present review results to the QP
- Balanced Score Card
- KPIs



## Workshops

During both days parallel workshops will be conducted in order to deepen the content of the lectures and to discuss practical aspects in detail.

Workshops will be offered on the following topics:

## Workshop 1

Deviation Management and Failure Investigation as Part of the Batch Record Review

#### Workshop 2

How to create a BRR SOP: Optimisation and Definition of relevant Processes

## Workshop 3

Organisation of a Batch Record Review

Each participant will have the opportunity to take part in 2 workshops! Please choose the ones you like to attend when you register for the course.

### **Speakers**

### Dr Bernhard Böhm, Boehringer Ingelheim

Dr Bernhard Böhm is Head of Project Management R&D Late Stage at the Boehringer Ingelheim, Germany. 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). Later he was QA manager at Solvay's production site in France.

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

Ingo Ebeling is responsible for the Technology and Production Support Unit at Abbott Products in Neustadt, Germany (the former Solvay Production Plant). This unit is the link between development and manufacturing and is also in charge for related process and product trouble-shooting activities. Before that, Ingo Ebeling was Head of Quality Assurance at the Neustadt site.

#### Ann McGee

Ann McGee Consulting Ltd., 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.

## Dr Monika Schlapp, Boehringer Ingelheim

Dr Monika Schlapp is Qualified Person at Boehringer Ingelheim in Ingelheim, Germany. Before working for Boehringer Ingelheim, she was Validation Manager in pharmaceutical production at Pharmacia.

### **Social Event**

On the evening of 29 March you are cordially invited to a social event in Vienna. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



Reservation Form: CONCEPT HEIDELBERG P.O. Box 10 17 64 69007 Heidelberg Germany



Country

Zip Code

Purchase Order No, if applicable

Important: Please indicate your company's VAT ID Number

Street/P.O. Box

Department

e-mail: info@concept-heidelberg.de Internet: www.gmp-compliance.org

•	8	ý	١	
Ĺ	3	,	ı	
	=		۱	

enna, Austria

Plases choose TWO Workshops:	Efficient Batch Record Review, 29 - 30 March 2011, VI
Togodoo	Kecord Kevi
	Efficient Batch

Reservation Form (Please complete in full)

If the bill-to-address deviates from the specifications on the right,

please fill out here:

Deviation Management and Failure Investigation as Part of the Batch Record Review

How to create a BRR SOP: Optimisation and Definition of relevant Processes Organisation of a Batch Record Review

Äŗ. 

Ms.

riease choose IV

Workshop I

Workshop 2

Workshop 3

Fitle, first name, surname

Company

Fax +49 (0) 62 21/84 44 34 CONCEPT HEIDELBERG P.O. Box 101764

D-69007 Heidelberg GERMANY

 We are happy to welcome a substitute colleague at any time you cannot attend the conference you have two options: General terms and conditions

within 1 week prior to the conference 100 % until 2 weeks prior to the conference 10 % until 1 weeks prior to the conference 50 %

2. If you have to cancel entirely we must charge the following processing fees: 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)! Important: This is a binding registration and above fees are due in case of cancellation or Terms of payment: Payable without deductions within 10 days after receipt of invoice.

to inform us in writing. The cancellation

non-appearance. If you cannot take part, you

E-Mail (please fill in)

Phone/I

Cit/

Date

Tuesday, 29 March 2011, 10.30 - 17.30 h (Registration and coffee 10.00 h- 10.30 h) Wednesday, 30 March 2011, 08.30 - 15.30 h

Venue

Renaissance Wien Hotel Linke Wienzeile/Ullmannstr. 71 1150 Vienna Austria

Phone +43 1 89 102 +43 1 89 102 300 Fax

**Fees** 

ECA Members EUR 1,490.- per delegate plus VAT EQPA Members EUR 1,490.- per delegate plus VAT APIC Members EUR 1,590.- per delegate plus VAT Non-ECA Members EUR 1,690.- per delegate plus VAT EU GMP Inspectorates EUR 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 event. Please use this form for your room reservation or be sure to mention "VA 6865 ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 15 February 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 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 +49-62 21 / 84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Jessica Stürmer (Organisation Manager) at +49-62 21 / 84 44 43 or per e-mail at stuermer@concept-heidelberg.de.