ECA Certified QA Manager Course*

Two Case Studies:
- Electronic Batch Record
- How to reduce Review Time

Three Workshops:
- Deviation Management and Failure Investigation
- Batch Record Review SOP
- Batch Record Review Organisation

Efficient Batch Record Review

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

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

ECA
EUROPEAN COMPLIANCE ACADEMY

This course is supported by:

QP ASSOCIATION

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

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 troubleshooting 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.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Efficient Batch Record Review, 29 - 30 March 2011, Vienna, Austria

Please choose TWO Workshops:

- ☐ 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

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number Purchase Order No, if applicable

Street/P.O. Box

City Zip Code Country

Phone/Fax E-Mail (please fill in)

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

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

D-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)!

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
Fax +43 1 89 102 300

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

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