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

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

Efficient Batch Record Review

Batch Manufacturing Documents: Recent Developments and Best Practices

26-27 June 2014, Budapest, Hungary

SPEAKERS:

Fionnuala Burke
McGee Pharma International

Jakub Čierný
SOTIO a.s.

Ann McGee
McGee Pharma International, 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 SOP Optimisation
- Case Studies
  - Electronic Batch Record
  - How to reduce Review Time

ECA 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

26-27 June 2014, Budapest, Hungary

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.

Programme

Regulatory Requirements applying to Batch Record Review

- EU Regulations
- FDA
- ICH Q7 requirements
- Regulations Update and Latest Developments in Industry
  - Consequences of ICH Q9/ Q10 and EU-GMP Chapter 1
  - Consequences of the Counterfeit Directive

Pharmaceutical Documentation & the Quality System

- How documentation fits into the Quality System of recommendation and regulations
- Important data for Quality Assurance
- Risk Assessment and Continuous Improvement
- The link to Operational Excellence and validated automated systems
- Review matrix
- Discussion of possible structures

How to handle the Documentation: Batch Documentation Life Cycle

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

The Design of the Master Batch Documentation

- Is there a need for re-design?
- Important aspects to consider
- How to gain efficiency

Steps to consider for a successful Batch Record Review Preparation

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

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

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 successfully execute Kaizen events

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

Three 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 optimize your Batch Record Review flow: The way from status quo to an ideal state

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.

Summary and Take Away Message

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

Speakers

Fionnuala Burke

McGee Pharma International

Fionnuala Burke is Pharmaceutical Quality Consultant. Before that she was, amongst others, Site GMP Training Co-ordinator and a Documentation Redesign - QA Specialist for Leo Pharma in Ireland. In this role she successfully reduced the complexity, discrepancies and errors associated with GMP documents and batch documentation.

Jakub Cierný

SOTIO a.s.

Jakub Cierný is GMP Regulatory Affairs Manager and Qualified Person (QP) at Sotio a.s., Czech Republic. Before that he was Head of QA/QC and Qualified Person at Orifarm Supply s.r.o. He studied at the Pharmaceutical Faculty of Charles University and did his Masters Thesis at University of Helsinki, Finland.

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.

Dr Monika Schlapp

Boehringer Ingelheim

Dr Monika Schlapp is Head of Quality Operations at Boehringer Ingelheim Ellas A.E., Greece. Before that she was Qualified Person at Boehringer Ingelheim in Ingelheim, Germany and Validation Manager at Pharmacia.

Social Event

On the evening of 26 June 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.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Efficient Batch Record Review, 26-27 June 2014, Budapest, Hungary

Please choose TWO Workshops:

☐ ☐ Workshop 1 Deviation Management and Failure Investigation as Part of the Batch Record Review
☐ ☐ Workshop 2 How to optimize your Batch Record Review flow: The way from status quo to an ideal state
☐ ☐ 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)

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

Thursday, 26 June 2014, 09.30 – 18.00 h
(Registration and coffee 09.00 h– 09.30 h)
Friday, 27 June 2014, 08.30 - 15.30 h

Venue

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

Fees*

ECA Members EUR 1,490.-
EQPA Members EUR 1,490.-
APIC Members EUR 1,590.-
Non-ECA Members EUR 1,690.-
EU GMP Inspectorates EUR 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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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

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* per delegate plus VAT