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 ČCierný
  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

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

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager“. Please find details at www.gmp-certification.eu
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**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.
Reservation Form (Please complete in full)

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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

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.

Conference language
The official conference language will be English.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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

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 of cancellation or non-appearance, we will not have received your payment, you are not entitled to participate in the conference, receipt of payment will not be confirmed.

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.:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21 / 84 44 51 or per e-mail at strohwald@concept-heidelberg.de.

* per delegate plus VAT

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