Efficient Batch Record Design and Review

Batch Manufacturing Documents: from Preparation to Operational Excellence

19-20 April 2016, Berlin, Germany

SPEAKERS:

Dr Bernhard Böhm
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Dr Monika Schlapp
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LEARNING OBJECTIVES:

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

- Process Improvement:
  - How to structure Batch Documentation
  - Systems and Tools for Batch Record Preparation and Review
  - Batch Record Flow and Review Optimisation
  - Batch Record Review Organisation

- Case Studies
  - Electronic Batch Record
  - How to reduce Review Time
  - How to use Operational Excellence Tools

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 of the batch record flow from the master to the 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 certified by a Qualified Person. However, over the years, documentation has become more and more extensive and the review can be very time-consuming, also because of complex master documents.

Furthermore, many observations made in inspections relate directly to the review of batch records. This fact clearly demonstrates the importance and challenge of implementing a GMP/FDA-compliant batch record design and review.

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 will cover all relevant aspects helping you to improve your batch records and their review.

**Target Group**

This Education Course is designed for all persons in Production and Quality Units who deal with the design and review of batch 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, Pharmaceutical Documentation & the Quality System**

- EU Regulations
- FDA
- ICH Q7 requirements
- Regulations Update and Latest Developments in Industry
- How documentation fits into the Quality System of recommendation and regulations
- Important data for Quality Assurance
- Risk Assessment and Continuous Improvement

**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 from paper based to EBR
- Master approval
- How efficient is an EBR system?
- Challenges in the introduction phase
- Electronic Batch Record Review

**Two Case Studies on Operational Excellence: Tools to reduce Batch Record Review Time**

- Tools and philosophy
- Batch record work stream reduction
- How to successfully execute Kaizen events
- Re-Design of batch records
- Right first time project

**Social Event**

On the evening of 19 April you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.
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

Dr BERNHARD BÖHM,
Boehringer Ingelheim, Germany
Bernhard Böhm is Vice President Global Product Lifecycle Management Operations. After joining the pharmaceutical industry at Solvay Pharmaceuticals, he held various positions in production, QA and Regulatory Compliance at Solvay’s German and French manufacturing sites. Within Boehringer Ingelheim, he headed R&D Project Management units in Germany and the US.

JAKUB CIERNY,
SOTIO a.s., Czech Republic
Jakub Cierny 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 in Prague and did his Masters Thesis at the University of Helsinki, Finland.

COLETTE DOLAN,
McGee Pharma International, Ireland
Colette Dolan is Senior Quality & Technical Specialist. Before that she was employed by Pfizer and held several positions within Quality Assurance and Compliance, including regulatory inspection support, senior QA Auditor and Qualified Person.

INGO EBELING,
Abbott Laboratories, Germany
Ingo Ebeling is responsible for the Technology Center (Manufacturing Science & Technology) at the Abbott Laboratories production plant in Neustadt, Germany. This unit is the link between development and manufacturing and is also in charge for related analytical, process and product optimization and troubleshooting activities. Ingo has a history in QA, Business Excellence and logistics.

Dr MONIKA SCHLAPP,
Boehringer Ingelheim Ellas, Greece
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.
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

Mr.    Miss.

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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City

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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:

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

CONCEPT HEIDELBERG reserves the right to change the materials, in-structors, 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 fee paid. CONCEPT HEIDELBERG will not be responsible for discount airline 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 all fees are due in case of cancellation or non-attendance. 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 informing 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)!

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Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form / POG when you have registered directly with the hotel. Early reservation is recommended.

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany

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APIC Members / FOPA Members € 1,490
Non-ECA Members € 1,590
ECA Members / EQPA Members € 1,690

Fees (per delegate plus VAT)

EU GMP Inspectorates € 845

The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on both days and all refreshments. VAT is reclaimable.

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