# Efficient Batch Record Design and Review

## Batch Manufacturing Documents: from Preparation to Operational Excellence

19-20 April 2016, Berlin, Germany

SPEAKERS:

Dr Bernhard Böhm
*Boehringer Ingelheim*

Jakub Cierny
*SOTIO a.s.*

Colette Dolan
*McGee Pharma International*

Ingo Ebeling
*Abbott Laboratories*

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 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

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 Design and Review

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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.

## 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.

## 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

### 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.

## 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:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

**Efficient Batch Record Design and Review,** 19-20 April 2016, Berlin, Germany

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)

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)! (As of January 2012)

**Privacy Policy:** By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

### Date

Tuesday, 19 April 2016, 09.30 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 20 April 2016, 09.00 - 15.30 h

### Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7-799

### Fees (per delegate plus VAT)

ECA Members / EQPA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 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 / POG 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

ECA has entrusted Concept Heidelberg with the organisation of this event.

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