ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Bernhard Böhm
Boehringer Ingelheim Vetmedica

Jakub Čierný
SOTIO

Ingo Ebeling
Abbott Laboratories

Dr Felix Kern
Merck

Dr Monika Schlapp
Boehringer Ingelheim Vetmedica

Efficient Batch Record Design and Review

Batch Manufacturing Documents: from Preparation to Operational Excellence

29/30 April 2025, Hamburg, Germany

On-site with two Workshops and several Q&A Sessions

Highlights

- Background and GMP Requirements
  - Regulatory Requirements
  - What do Authorities expect?
  - Good Documentation Practice
- Practical Implementation
  - From design to final approval
  - Examples
- Process Improvement:
  - Efficiency in the review process
  - Operational Excellence tools and how to use them
  - The use of Electronic Batch Record systems

Objectives

During this live Education Course, you will hear about 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.

During this Education Course, experts will cover a**ll relevant aspects helping you to improve your batch records and their review.**

Target Audience

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.

Moderator

Wolfgang Schmitt,
Concept Heidelberg (on behalf of ECA)

Social Event

In the evening of the first day, you are cordially invited to a social event (city tour and Dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Programme

Part 1: Background and GMP Requirements

Regulatory Requirements applying to Batch Record Review, Pharmaceutical Documentation & the Quality System

- Part 1: Batch Record Review
  - Cost of Quality
  - Relevant GMP Guidelines: EU, US, ICH
  - Regulations update with impact on documentation
  - Documentation and FDA Warning Letters
- Part 2: Pharmaceutical Documentation and the Quality System
  - How batch documents fit into the Quality System
  - Important data for Quality Assurance
  - Risk Assessment and continuous improvement
  - The link to Operational Excellence and validated automated systems
  - Review Matrix
  - Possible structures

The Design of the Master Batch Documentation

- Important aspects to consider
- How to gain efficiency

Batch Record Design and Review in pharmaceutical Development (Case Studies)

- Differences from the commercial batch records
- Expectations from batch record in development
- Different scenarios (stucture, deviation, changes, training, review process)

Part 2: Practical Implementation

From the MBR Design to final Approval (Presentation and Workshop)

- MBR Design and Approval
- Ways to optimise
- Responsibilities
- Paper-based vs electronical MB
- Examples

Part 3: Possibilities for Process Improvement

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

Operational Excellence Tools to reduce Batch Record Review Time

- Background
- How to use Kaizen
- Project: "Batch record reduction / flow optimization"

How to optimise your Batch Record Review Flow (Presentation and Workshop)

The way from status quo to an ideal state

Electronic Batch Record – A competitive Advantage?

- Legal background
- Minimum requirements
- What needs to be considered?
- Advantages
- Case Study

QA Oversight on EBR Validation Activities

- Validation Life Cycle
- Qualification activities
- Maintenance
- Training

Speakers

Dr Bernhard Böhm,
Boehringer Ingelheim Vetmedica, Germany

Bernhard Böhm is Vice President and Head of External Manufacturing Animal Health. Before that he was - amongst others - Site Head Toulouse at Boehringer Ingelheim France, Factory Head and Vice President Global Product Lifecycle Management Operations.

Jakub Čierný,
SOTIO a.s., Czech Republic

Jakub Čierný is a Senior Quality Compliance 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.

Ingo Ebeling,
Abbott Laboratories, Germany

Ingo Ebeling is Site Director Hannover and also responsible for the MST (Manufacturing Science & Technology) and Engineering Department at the Abbott Laboratories site in Neustadt, Germany. Ingo has a history in QA, Business Excellence and logistics.

Dr Felix Kern,
Merck, Germany

Felix Kern is Associate Director and Head of Compliance Launch and Technology Center. Before that, he was – amongst others – Head of Production Bulk.

Dr Monika Schlapp,
Boehringer Ingelheim Vetmedica, Germany

Dr Monika Schlapp is Director Global Quality Animal Health at Boehringer Ingelheim Vetmedica. Before that she was amongst others Product Lifecycle Manager in Operations, Site Quality Head and Qualified Person.

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GERMANY

Reservation Form (Please complete in full)

Efficient Batch Record Design and Review
29/30 April 2025, Hamburg, Germany

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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:
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- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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, 29 April 2025, 9.00 h – 17.30 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 30 April 2025, 8.30 h – 15.30 h

Venue
Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany
Phone +49 (0) 40/ 22 63 62 0
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Fees (per delegate, plus VAT)
ECA Members / EQPA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes lunch on both days, dinner on day one and all refreshments.

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 course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21538.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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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