



Speakers



Dr Bernhard Böhm
Boehringer Ingelheim, France



Jakub Čierný
SOTIO, Czech Republic



Ingo Ebeling
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Dr Monika Schlapp
Boehringer Ingelheim Vetmedica,
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Roger Smith
Redwood Pharma Consulting, U.K.

This course is supported by



Efficient Batch Record Design and Review

Batch Manufacturing Documents:
from Preparation to Operational Excellence



Live Online Training on 14/15 February 2023



Highlights

- 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
 - Risk Management Applications
- Case Studies
 - Serialisation
 - Electronic Batch Record
 - Operational Excellence
 - Failure Investigation
 - Master Batch Design
 - BRR in Development

Objectives

During this live online 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 **all 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)

Programme

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

- Global regulations and expectations
- Regulations Update and Latest Developments in Industry
- How documentation fits into the Quality System of recommendations and regulations
- Important data for Quality Assurance
- Risk Assessment and Continuous Improvement

The Design of the Master Batch Documentation

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

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

Risk Assessment/ Management Applications within the Batch Record Process

- How the risk lifecycle links with the BRR stages:
 - Risks associated with paper and electronic records
 - Risks associated with people checking documentation
 - Relative risk factors
 - Risks associated with the process
 - Risks for QP 'discretion'
- Quality Risk Management
 - Impact the effectiveness of deviations, OOS and Change Controls
 - Improvement of root cause investigations

QA Oversight on EBR validation activities

- Validation Life Cycle
- Qualification activities
- Maintenance
- Training



Question and Answer Sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.



Case Studies:

- Operational Excellence - Tools to reduce Batch Record Review Time
- Electronic Batch Record (EBR) – a competitive Advantage?
- Serialisation - from Master Batch Documentation to Batch Release
- Failure Investigation
- Design of a Master Batch Documentation/ Protocol
- Batch Record Design and Review in pharmaceutical Development

Your Benefits:

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires:

„... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“

This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.



This Training Course is recognized for the GMP/GDP Certification Scheme "Certified Quality Assurance Manager"



Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-year period – allowing you to broaden your knowledge in GMP and GDP compliance.

Please find more information at www.gmp-certification.org

Speakers



Dr Bernhard Böhm,
Boehringer Ingelheim, France

Bernhard Böhm is Site Head Toulouse at Boehringer Ingelheim. Before that he was amongst others 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 Monika Schlapp,
Boehringer Ingelheim Vetmedica, Germany

Dr Monika Schlapp is Global Quality Head „Launch, Transfer & Projects“ at Boehringer Ingelheim Vetmedica. Before that she was amongst others Product Lifecycle Manager in Operations, Site Quality Head and Qualified Person.



Roger Smith,
Redwood Pharma Consulting, U.K.

Roger held Operational Quality, Audit Manager and Audit Director positions with GlaxoSmithKline until 2014, when he set up his own consultancy business.

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)



Efficient Batch Record Design and Review Live Online Training on 14/15 February 2023

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)

CONCEPT HEIDELBERG
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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 %

- Cancellation until 1 week prior to the conference 50 %

- Cancellation 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.

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sponsible for discount airfare penalties or other costs incurred due to a cancel-

lation.

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cellation or non-appearance. If you cannot take part, you have to inform us in

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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 con-

ference (receipt of payment will not be confirmed!) (As of January 2012).

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

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cessed. 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 <https://www.gmp-compliance.org/privacy-policy>). 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 of the Live Online Training

Tuesday, 14 February 2023, 9.00 – 17.00 h

Wednesday, 15 February 2023, 9.00 - 17.00 h

All times mentioned are CET.

Technical Requirements

We use Webex Events for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

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.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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