ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Bernhard Böhm
Boehringer Ingelheim

Jakub Cierny
SOTIO a.s.

Ingo Ebeling
Abbott Laboratories

Dr Monika Schlapp
Boehringer Ingelheim

Roger Smith
Redwood Pharma Consulting

This course ist supported by

QP Association

Efficient Batch Record Design and Review

Batch Manufacturing Documents: from Preparation to Operational Excellence

17/18 June 2020 | Prague, Czech Republic

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
  - How to use Operational Excellence Tools
  - BRR in Development

Objectives

During this course, you will be able to discuss 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

Participants' comments:

Excellent trainers, full of knowledge and experience. Thanks!"
Natasa Kalanj, Hemofarm AD, Serbia

„Workshops were very useful."
García Poultier Patricio, GADOR S. A.

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
  - Using QRM to perform a SWOT analysis
  - What does a good risk assessment look like?

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
- Batch Record Design and Review in pharmaceutical Development

QA Oversight on EBR validation activities

- Validation Life Cycle
- Qualification activities
- Maintenance
- Training

Workshop:

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 optimise your Batch Record Review flow:
The way from status quo to an ideal state

Workshop 3
Design of a Master Batch Documentation/ Protocol

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.

Social Event

In the evening of the first course day, 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.

Speakers

Dr Bernhard Böhm, Boehringer Ingelheim, Germany

Bernhard Böhm is Factory Head at Boehringer Ingelheim. Before that he headed R&D Project Management units in Germany and the US and was 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 responsible for the Technology Center (Manufacturing Science & Technology) at the Abbott Laboratories production plant in Neustadt, Germany. Ingo has a history in QA, Business Excellence and logistics.

Dr Monika Schlapp, Boehringer Ingelheim, Germany

Dr Monika Schlapp is Head of Process Development Teams, Global Department Launch and Transfer. Before that she was Head of Quality Operations at Boehringer Ingelheim Ellas A.E., Greece and Qualified Person at Boehringer Ingelheim in Ingelheim, Germany.

Roger Smith, Redwood Pharma Consulting

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:

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CONCEPT HEIDELBERG
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GERMANY

Reservation Form (Please complete in full)

Efficient Batch Record Design and Review | 17/18 June 2020, Prague, Czech Republic

Please choose TWO Workshops:

☐ *Workshop 1 Deviation Management and Failure Investigation as Part of the Batch Record Review*
☐ *Workshop 2 How to optimise your Batch Record Review flow: The way from status quo to an ideal state*
☐ *Workshop 3 Design of a Master Batch Documentation/Protocol*

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:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks 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.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill 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).
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 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

Wednesday, 17 June 2020, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 18 June 2020, 08.30 - 15.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Email prague@corinthia.com

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 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 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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Ms Nicole Bach (Organisation Manager) at
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