ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Bernhard Böhm
Boehringer Ingelheim

Jakub Čierný
SOTIO

Ingo Ebeling
Abbott Laboratories

Dr Felix Kern
Merck

Dr Monika Schlapp
Boehringer Ingelheim Vetmedica

This course ist supported by
QP Association

Efficient Batch Record Design and Review

Batch Manufacturing Documents: from Preparation to Operational Excellence

Live Online Training on 15/16 February 2024

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 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 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)

Programme

Part 1: Background and GMP Requirements

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

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

- Differences from the commercial batch records
- Expectations from batch record in development
- Different scenarios

Part 2: Practical Implementation

From the MBR Design to final Approval

- Creation of the Master Batch
- Generation of the batch documentation (who, what, how)
- The path through production.
- Review process (who, what, how)
- QP involvement
- Site kick: what if individual process steps take place at a third party
- 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"

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

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.

Speakers

Dr Bernhard Böhm, Boehringer Ingelheim, 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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Reservation Form (Please complete in full)

Efficient Batch Record Design and Review
Live Online Training on 15/16 February 2024

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)

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If you cannot attend the conference you have two options:
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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 of the Live Online Training
Thursday, 15 February 2024, 9.00 – 17.00 h
Friday, 16 February 2024, 9.00 - 15.00 h
All times mentioned are CET.

Technical Requirements
We use Webex 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

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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