ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Bernhard Böhm
Boehringer Ingelheim France

Jakub Čierný
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

Live Online Training on 23/24 September 2021

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 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

Robert Schwarz, FH Campus Vienna

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?

QA Oversight on EBR validation activities

- Validation Life Cycle
- Qualification activities
- Maintenance
- Training

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 as Part of the Batch Record Review
- Design of a Master Batch Documentation/ Protocol
- Batch Record Design and Review in pharmaceutical Development

Your Benefits:

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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.

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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 responsible for the MST (Manufacturing Science & Technology) and Engineering Department at the Abbott Laboratories production plant 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 Animal Health. Before that she was amongst others Product Lifecycle Manager in Operations, Site Quality Head and Qualified Person.

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.

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Reservation Form (Please complete in full)

Efficient Batch Record Design and Review
Live Online Training on 23/24 September 2021

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 %,
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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 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 of the Live Online Training
Thursday, 23 September 2021, 09.00 – 17.30 h
Friday, 24 September 2021, 08.30 - 15.00 h
All times mentioned are CEST.

Technical Requirements
For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer 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.

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

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