ECA Academy
Your GMP/GDP Information Source

Efficient Batch Record Design and Review

Batch Manufacturing Documents: from Preparation to Operational Excellence

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

28-29 May 2019, Vienna, Austria

LEARNING OBJECTIVES:

- 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
- Case Studies
  - Serialisation
  - Electronic Batch Record
  - How to reduce Review Time
  - How to use Operational Excellence Tools

This course is supported by:

QP Association

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager".
Please find details at www.gmp-certification.eu

Efficient Batch Record Design and Review

28-29 May 2019, Vienna, Austria

Learning 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.

Furthermore, many observations made in inspections relate directly to the review of documents. This fact clearly demonstrates the importance and challenge of implementing a GMP/FDA-compliant Batch Record Review.

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

Target Group

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.

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.

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

Steps to consider for a successful Batch Record Review Preparation

- Line clearance
- Process steps
- Changes during the process
- Deviations in production
- Certificates of analysis

Case Study:

- Serialisation - from Master Batch Documentation to Batch Release

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

Case Study: Electronic Batch Record (EBR) – a competitive Advantage?

- Transition from paper based to EBR
- Master approval
- How efficient is an EBR system?
- Challenges in the introduction phase
- Electronic Batch Record Review

Participants' comments:
„Excellent trainers, full of knowledge and experience. Thanks!"
Natasa Kalanj, Hemofarm AD, Serbia
(2016 course)

„Workshops were very useful."
García Poultier Patricio, GADOR S. A
(2017 course)

QA Oversight on EBR validation activities

- Validation Life Cycle
- Qualification activities
- Maintenance
- Training

Two Case Studies on Operational Excellence: Tools to reduce Batch Record Review Time

- Tools and philosophy
- Batch record work stream reduction
- How to successfully execute Kaizen events
- Re-Design of batch records
- Right first time project

Workshops

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.

Speakers

DR BERNHARD BÖHM

Boehringer Ingelheim, Germany
Bernhard Böhm is Vice President Global Product Lifecycle Management Operations. After joining the pharmaceutical industry at Solvay Pharmaceuticals, he held various positions in production, QA and Regulatory Compliance at Solvay's German and French manufacturing sites. Within Boehringer Ingelheim, he headed R&D Project Management units in Germany and the US.

JAKUB CIERNÝ

SOTIO a.s., Czech Republic
Jakub Cierný is a Senior Quality Compliance Manager and Qualified Person (QP) at SOTIO a.s., Czech Republic. SOTIO is developing autologous cell therapy products what brings various challenges into batch record design and review. 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 & Tech nology) at the Abbott Laboratories production plant in Neustadt, Germany. This unit is the link between development and manufacturing and is also in charge for related analytical, process and product optimization and troubleshooting activities. 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. He has published several articles in GMP Review and continued to provide proactive support in the areas of quality improvement, regulatory inspection preparation, GMP training and quality risk management.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Efficient Batch Record Design and Review, 28-29 May 2019, Vienna, Austria

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

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number Purchase Order No, if applicable

Street/P.O. Box

City Zip Code Country

Phone/Fax E-Mail (please fill in)

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.

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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.

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Date

Tuesday, 28 May 2019, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday 29 May 2019, 08.30 - 15.30 h

Venue

Radisson Blu Park Royal Palace Hotel
Schlossallee 8
1140 Vienna, Austria
Phone +43 (1) 891 10 - 0
Fax +43 (1) 891 10-9090
info.parkroyalpalace.vienna@radissonblu.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 event. 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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w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
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