ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Marcus Heinbuch
B.Braun Melsungen, Germany

Mick Hopper
GxPpro, U.K.

Dr Jens-Uwe Rengers
JeRo Consulting, Switzerland

Sandra Schäffler
GMP/GDP Inspectorate, Germany

NEWS

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Deviation Management and CAPA

11/12 March 2025, Barcelona, Spain

Highlights

- Rules and Regulations
- Deviations and CAPA
  - Classification
  - Failure Investigation and Root Cause
  - Risk Management
  - Human Error
- Case Studies:
  - CAPA System Implementation
  - Deviations in Microbiology
  - Implementation of an electronic System
- Evaluating and Monitoring
  - Effectiveness of CAPAs
  - KPIs

With Workshop, Examples and Q&A Sessions

Objectives

During this training course, you will get to know the principles and discuss all relevant aspects to **implement, improve and/ or work with a Deviation Management and CAPA System.** Furthermore, you will get to know possibilities and tools to **monitor and evaluate your CAPAs**.

Background

Things will go wrong from time to time. In the world of pharmaceuticals, we need to ensure that we have robust processes and procedures in place to deal with such situations. When an unplanned event arises it must be handled accordingly.

FDA's **Quality System Guide, recent Warning Letters and EU-GMP Chapter 1** clearly emphasise the increasing relevance of a proper deviation management and CAPAs. **ICH Q9** on Quality Risk Management and **ICH Q10** on Pharmaceutical Quality Systems empower us to handle issues that arise in our daily work on the basis of risk analysis.

In any case a **sound failure investigation** is the key to identify appropriate CAPAs. Here it is also important to know how to deal with human error based and non-human error based non-conformances.

Independent from that, it needs to be pointed out that **CAPA is an excellent Quality Management tool** to continuously improve processes and avoid future failures. All personnel involved in the management of deviations and CAPAs should aim to identify opportunities for further improvement.

Target Audience

This course is designed for all personnel involved in Deviation Management and CAPA activities at their company. It is addressed to persons from Quality Assurance and Control, Manufacturing and R&D.

Participant comment:
„Very well structured and always on time according to the agenda."
Dr Martina Schlick, Axolabs GmbH

Programme

Expectations in dealing with Deviations and CAPAs from the Perspective of the Authority

- Focus in inspections
- Documentation of deviations and CAPAs with deadlines for processing
- Trend analysis of deviations within the scope of the PQR
- Recording of deviations as part of the self-inspection
- Initiation of CAPA

Excerpt from FDA Warning Letter
"...the investigation failed to establish a root cause and your quality unit failed to ensure the implementation of adequate corrective actions to prevent future recurrence."

Deviation Handling

- How to document deviations
- Information and Data Management
- Critical/ major/ minor
- CAPA or not?

CAPA: Principles, System, Implementation and Process Improvements and the use of Risk Management Techniques

- Root Cause Analysis Tools
- Quality Risk Management
- Human Error Overview
- Monitoring & Evaluation Overview

Workshop:
An interactive exercise on scenarios with a focus on using the tools from the presentation

- Human error based
- Non-human error based

Harmonisation in dealing with Deviations at international Level

- Regulations of the FDA and the WHO Expert Committee on Specifications for Pharmaceutical Preparations and comparison with the European requirements
- Exchange of experience in dealing with deviations in third countries and regulatory requirements exemplified by India
- Goal: Harmonisation at international level

Case Study: How to implement a CAPA System

- How to integrate existing QM Systems (OOS, Complaint Handling, Deviations)
- Examples and lessons learned

Case Study: Implementation of a Software Tool for CAPA Management

- Understanding your workflows and processes
- Can you improve the current process using electronic workflows?
- Efficient validation of a CAPA application

CAPA Effectiveness & System Performance Check

- CAPA Effectiveness
  - Why assessing effectiveness
  - The meaning of effectiveness
  - Determine effectiveness
- System Performance
  - Performance Monitoring
  - Examples of Performance Indicators

Questions & Answers

Sufficient time has been set aside to answer your questions.

Social Event

In the evening of the first day, you are cordially invited to a social event (city tour and Dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Marcus Heinbuch
B.Braun Melsungen AG, Germany

Marcus Heinbuch is Head of QM Operations in the Quality Management of CoE Pharmaceuticals.

Michael Hopper
GxPpro, U.K.

Michael (Mick) Hopper set-up GxPpro after leaving Pfizer. Mick has over 30 years experience and held several Technical, Management and QA roles.

Sandra Schäffler
GMP Inspectorate, Local Government Munich, Germany

Sandra Schäffler is a Pharmacist and GMP/GDP/GFP Inspector.

Dr Jens-Uwe Rengers
JeRo Consulting, Switzerland

Prior to the funding of his consultancy business, Jens-Uwe Rengers acted as General Manager at Akorn AG. Before that he was Director Quality and QP and held different other roles at Byk Gulden (now Takeda), Cytos Biotechnology AG and Siegfried Ltd.

Your benefits:

This Training Course is recognized for the GMP/GDP Certification Scheme "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-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Deviation Management and CAPA | 11/12 March 2025, Barcelona, Spain

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 4 weeks prior to the conference 10 %,
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- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will 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 July 2022).
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
Tuesday, 11 March 2025, 09.00 – 17.30 h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 12 March 2025, 08.30 – 15.30 h

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Tel. +34 (93) 503 53 00
E-Mail: sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice and includes lunch on both days, dinner on the first day and all refreshments.

Accommodation
CONCEPT 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.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21642.

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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