



Speakers



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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 Live Online Training, 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



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.

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.

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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Reservation Form (Please complete in full)

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Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

CONCEPT HEIDELBERG

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ZIP Code

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Phone / Fax

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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

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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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