ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

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Deviation Management and CAPA

14/15 June 2022 | Berlin, Germany

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

Workshops on:
- Process Analysis and Failure Investigation
- CAPA Effectiveness & System Performance Check

Objectives

During this 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.

Programme

International Requirements – Rules and Regulations

- European requirements
- The expectations of the FDA
- GMP and documentation issues
- Harmonisation in sight?

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

- 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

Deviations in the Light of Inspections

- Focus in inspection
- Trends, Product Quality Review and Product Review
- Self-inspection as an important tool

Case Study:
How to implement a CAPA System

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

Case Study: How to deal with Microbiological Deviations

- Contamination control and company culture
- What QA needs to understand
- Interface with QA and production
- OOS vs. deviation in the microbiological laboratory
- Possible CAPAs

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

Workshop on CAPA Effectiveness & System Performance Check

An interactive session with a focus on enhancing the knowledge gained in the presentation.

Marcus Heinbuch
B.Braun Melsungen AG, Germany

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

Dr Ulrich Herber
Charles River Microbial Solutions International Ltd., Ireland

Dr Ulrich Herber is Director of Technology and Market Development - Microbial Solutions.

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.

Lea Joos
GMP Inspectorate, Local Government Munich, Germany

Lea Joos is a Pharmacist working for the local Inspectorate as GMP and GDP Inspector.

Manuel Suhrada
Boehringer Ingelheim, Austria

Manuel Suhrada is Head of Site Quality Systems at the Boehringer Ingelheim site in Vienna. Before that he was Head of Deviation & CAPA Management, GMP-Officer and corp. Process Owner at Octapharma Pharmazeutika.

Your benefits:

Internationally Acknowledged Certificate from ECA Academy

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.

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)

Deviation Management and CAPA | 14/15 June 2022, Berlin, Germany

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)

CONCEPT HEIDELBERG
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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
Tuesday, 14 June 2022, 09.00 – 17.45 h
(Registration and coffee 08.30 – 9.00 h)
Wednesday, 15 June 2022, 08.30 – 16.00 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
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On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on site event, it will be conducted live online. In this case, you will be informed in due time.

Fees (per delegate, plus VAT)
ECA 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 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 course. 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.

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.

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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