ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

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Mick Hopper
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NEWS

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Deviation Management and CAPA

Live Online Training on 20/21 March 2024

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 many Examples, Polls and Q&As

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

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

Process Analysis and Failure Investigation

Scenarios with a focus on using the tools from the presentation before:

- 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

Question & Answer Sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

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.

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:

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 | Live Online Training on 20/21 March 2024

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)

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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Wednesday, 20 March 2024, 09.00 – 16.30 h
Thursday, 21 March 2024, 09.00 – 16.30 h
All times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

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.

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.

You cannot attend the Live Event?

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Organisation and Contact

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

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