ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Martin M. Appel
Switzerland

Marcus Heinbuch
B.Braun Melsungen AG, Germany

Dr Ulrich Herber
Charles River, Ireland

Mick Hopper
GxPpro, U.K.

Lea Joos
GMP/GDP Inspectorate, Germany

Deviation Management and CAPA

19/20 May 2020 | Hamburg, 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.

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

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

As part of the periodic quality review programme, Quality Management should routinely analyse reports of deviations and CAPAs to determine KPIs, trends, recurrence of non-conformances and effectiveness of CAPAs.

A summary overview should be reported to the Senior Management team. ICH Q10 identifies this as best practice - but are we doing this as well as we could or should?

We will discuss Quality Metrics as well as which are the important ones that will show you have a good Pharmaceutical Quality System.

Workshop on CAPA Effectiveness & System Performance Check

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

Speakers

Dr Martin M. Appel
Switzerland

Dr Appel was Director QA for the Global API External Manufacturing and Supplier Quality of Janssen Supply Chain. He has more than 30 years experience in several manager positions in the pharmaceutical industry.

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.

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GERMANY

Reservation Form (Please complete in full)

Deviation Management and CAPA | 19/20 May 2020, Hamburg, 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)

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Date
Tuesday, 19 May 2020, 09.00 – 17.45 h
(Registration and coffee 08.30 – 9.00 h)
Wednesday, 20 May 2020, 08.30 – 16.00 h

Venue
Barceló Hotel Hamburg
Ferdinandstraße 15
20095 Hamburg, Germany
Phone +49 40 22 63 62 0
Email hamburg@barcelo.com

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 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 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.

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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