ECA Academy
Your GMP/GDP Information Source

Speaker

Dr Karl-Heinz Bauer
Boehringer Ingelheim

CAPAs in QC Laboratories

Live Online Training on 14 January 2025

Highlights

- Regulatory requirements for CAPAs and CAPAs in quality control
- Understand and prevent human error
- Measures to avoid and prevent OOS results
- Practical examples & exercises
- Two Q&A sessions

With practical examples and exercises how to define adequate and effective CAPA measures

Objectives

In this Live Online Training you will learn how to introduce and maintain your CAPA system in quality control in accordance with GMP requirements. You will get to know how CAPA can be integrated into the QM system and which specific steps should be initiated to reduce the error rate in the laboratory.

You will get an overview of how you can use selected CAPA measures in quality control to help avoid errors and thus increase efficiency in analysis.

Background

The processing of laboratory errors is a legally mandatory but usually very time-consuming task in many laboratories. Expensive resources are tied up with troubleshooting and the implementation of repeat analyzes, which in turn reduces the efficiency of the laboratory.

In view of the growing cost pressure and the high complexity of many analytical devices and procedures, this is particularly problematic, because the increasing load encourages additional errors and thus causes a situation that is becoming increasingly difficult to resolve. The required quality of quality control can only be maintained or regained with suitable systematic procedures.

In the more recent regulations, CAPA is expressly required, so that the inspection relevance for it has increased steadily in recent years.

Target Audience

This Live Online Training is specifically designed for

- laboratory managers,
- GMP assistants,
- QA officer,

who have not yet developed systematic CAPA processes or are in the process of establishing or optimizing them.
Employees and managers from the pharmaceutical industry are also addressed, especially from the following laboratory areas:

- incoming goods inspection,
- in-process and finished goods control,
- analytical development,
- active ingredient and excipient testing,
- and contract/service laboratories.

Finally, the seminar is also developed for employees and managers from quality assurance units.

Moderator

Dr Markus Funk

Programme

Welcome and Introduction

CAPA and CAPA in QC Labs

- Terms and definitions
- Regulatory requirements
- Non-conformities
- Controlled handling of non-conformities
- The CAPA system
- Triggers of CAPA operations
- Structure of the CAPA process
- CAPA in quality control
- Classification and clustering of typical laboratory problems

Questions and Answers (Session 1)

Understanding and Preventing Human Errors

- What is human error?
- Definition, Categories, and psychology of human error
- The right attitudes and behaviors for adequate error investigations
- The vicious cycle of „guilt“
- The right „error culture“
- Snappy exercises

Concepts to Prevent Lab Errors in QC & Practical Exercise to Define Adequate CAPA Measures

- Terms, definitions, and requirements for error prevention
- Sources of errors, its investigation in the laboratory and the resulting prevention measures
- Development stages of an integrated quality, error, and improvement culture
- Typical deficiencies from health authority inspections
- Examples and practical exercises to define suitable CAPA measures

Questions and Answers (Session 2)

In two live discussion rounds, there is the opportunity to ask questions which will be answered by the speaker.

EU GMP Guidelines, Part I - Basic Requirements for Medicinal Products

1.4 A Pharmaceutical Quality System appropriate for the manufacture of medicinal products should ensure that [...]
An appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problems. This can be determined using Quality Risk Management principles. In cases where the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those.

EU GMP Guidelines, Part I - Basic Requirements for Medicinal Products

8.9 When a quality defect investigation is initiated, procedures should be in place to address at least the following: [...]
ix. The need for appropriate Corrective and Preventative Actions (CAPAs) to be identified and implemented for the issue, and for the assessment of the effectiveness of those CAPAs.

Your Benefit


CERTIFICATE

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.

Speaker

Dr Karl-Heinz Bauer
Boehringer Ingelheim International GmbH & Co. KG, Ingelheim

Karl-Heinz is a pharmacist with a PhD in pharmaceutical engineering and with Boehringer Ingelheim for 25 years in managerial positions in drug manufacturing, testing and quality assurance. Since January 1st, 2020, he has assigned to a strategic international quality management function.
He has worked for many years as a freelance trainer, consultant and coach in the pharmaceutical industry.

Timetable

13.00 – 13.15 h	Welcome and Introduction
13.15 – 14.30 h	**Presentation 1: CAPA and CAPA in QC Labs**
14.30 – 14.45 h	Break
14.45 – 15.30 h	**Presentation 2: Understanding and Preventing Human Errors**
15.30 – 15.45 h	**Q&A Session 1**
15.45 – 17.00 h	**Presentation 3: Concepts to Prevent Lab Errors in QC & Practical Exercise to Define Adequate CAPA Measures**
17.00 – 17.15 h	**Q&A Session 2**
17.15 – 17.30 h	Summary & Closing of the Seminar

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GERMANY

Reservation Form (Please complete in full)

CAPAs in QC Laboratories
Live Online Training on 14 January 2025, 13:00 – 17:30 h CET

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 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 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 of the Live Online Training

Tuesday, 14 January 2025, from 13:00 to 17:30 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 EUR 590.-
APIC Members EUR 640.-
Non-ECA Members EUR 690.-
EU GMP Inspectorates EUR 590.-
The conference fee is payable in advance after receipt of invoice.

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 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.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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