



Speaker



Dr Karl-Heinz Bauer
Trainer - Consultant - Coach
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CAPAs in QC Laboratories



Live Online Training on 10 February 2026



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.

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

Speaker



Karl-Heinz Bauer, PhD, Pharmaceutical Engineering
Trainer - Consultant - Coach
(previously with Boehringer Ingelheim)

Karl-Heinz worked as a pharmacist at Boehringer Ingelheim for 30 years in managerial national and international functions in pharmaceutical production, quality control and quality assurance. At the same time, he worked part-time as a freelance trainer and speaker for the pharmaceutical industry for many years. Since January 2025, he has been providing his experience, skills, and competencies to the pharmaceutical industry as a full-time freelance trainer, consultant, and coach.

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CAPAs in QC Laboratories
Live Online Training on 10 February 2026 from 13:00 – 17:30 h CET

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Date of the Live Online Training
Tuesday, 10 February 2026, from 13:00 – 17:30 h CET

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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 – **or search and register directly at www.gmp-compliance.org under the number 22096.**

Presentations/Certificate

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Conference language

The official conference language will be English.

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Organisation and Contact

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

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