Speakers

Energy Kristina Hansen
MilCor Consulting

Cecilie Hejlskov
Syntese

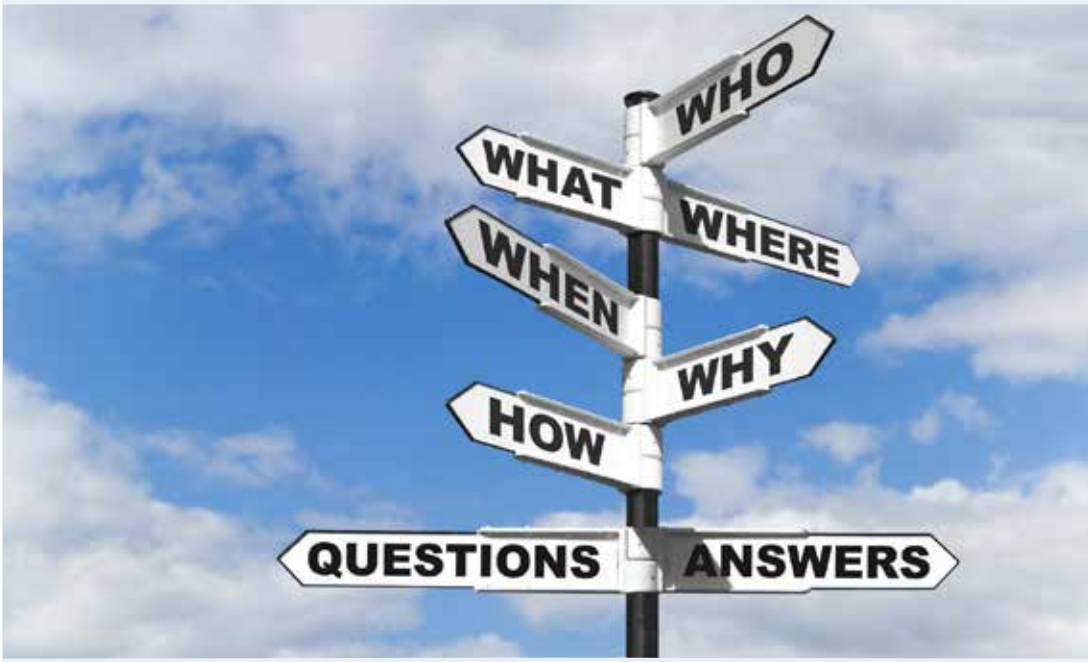
Tim Ohlrich
Gempex

Wolfgang Schmitt
Concept Heidelberg

Root Cause Analysis

A CAPA Workshop on Successful Failure Investigation

28/29 October 2025 | Hamburg Germany



Highlights

- Regulations and Background
- Human Error
- Tools presented:
  - 5 Whys
  - Ishikawa (Fishbone)
  - Comparative Analyses
  - Bow-Tie Risk Management
  - Problem-Solving Analysis
  - A3 Methodology
  - 3B Method (Behavioural Root Cause Analysis Tool)
- RCA Completion and Documentation

Programme

Objectives

During this course, you will get to know the principles and discuss all relevant aspects to perform **failure investigations to get to the true Root Cause of a problem**. This is the key for efficient Event Management and CAPA Systems.

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.

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EudraLex Vol. 4, EU-GMP Guidelines,
Chapter 1 (Pharmaceutical Quality System):
1.4 (xiv): "An appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problems."

In any case a **sound failure investigation** is the key to identify appropriate actions and CAPAs. Here, understanding how to handle both human error- and non-human error-based non-conformances is crucial.

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EudraLex Vol. 4, EU-GMP Guidelines,
Chapter 1 (Pharmaceutical Quality System):
1.8: [...] "The basic requirements of GMP are that: (vii) Any significant deviations are fully recorded, investigated with the objective of determining the root cause and appropriate corrective and preventive action implemented"

Root cause analysis (RCA) is a process that attempts to identify the exact cause of a problem, such as a deviation. Only by identifying the exact underlying fault it is possible to take the right action to solve the problem and prevent it from occurring again.

Target Audience

This course is designed for all personnel involved in failure investigation/Root Cause Analysis concerning events, deviations and CAPA activities in their company. It is addressed to persons from Quality Assurance and Control, Manufacturing and R&D.

Testimonial

"Very good and interesting course. A lot of take-home messages. Especially the human behavior/human error insights."
Sabine Evers, Ardena, The Netherlands

Programme

Kick-off: When it's human

- Expectations on humans
- Why human error could not be a root cause
- Blame culture vs. root cause
- Error culture

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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."

Presentation and Workshop: Using 5 Whys und Ishikawa

- Short Introduction of the methods
- Strengths and weaknesses of each method
- Typical mistakes in application
- Workshop: Real life examples and experiences

Interactive Session: Comparative Analysis

- Identifying and documenting errors with worksheets
- The need for a systematic approach
- The key for success: comparison of occurred deviations with available facts

Bow-Tie Risk Management and Problem Solving Analysis

- Controls, connection and causality
- Risk velocity
- Preventive- detective and corrective controls
- The link to Fault Tree Analysis and Event Tree Analysis

Interactive Session: A3 Methodology

- What is a problem?
- The causes investigation; point of cause, direct cause and root cause
- The 8-steps, structure and methodology
- Deep Dive: Point of cause analysis
- Solving a murder case

Human Error Related Deviations

- The What
  - Top 10 Categories: FDA Warning letters (2021 -2022)
  - The commonality
  - Undesirable behaviour...what is it?
- The How
  - The KAP model
  - Factor in the social element
- The Recurrence
  - Human error is NEVER a root cause
  - Blame it on the culture

Behavioural Root Cause Analysis (bRCA) for Human Error Related Deviations (HErD)

- Behavioural Root Cause Analysis tool (3B Method)
- Theory behind 3B method
  - Informative construct (brain)
  - Motivational construct (beating heart)
  - Perceived barriers construct (brick)
- Utilize the Solution
  - Sort the HErD - 3B method
  - Practice in groups

RCA Completion

- How to document a Root Cause Analysis
- How to define the right actions based on the outcome

Deviation Management and CAPA

Principles and all relevant aspects to implement, improve and/ or work with a Deviation Management and CAPA System are topic of ECA's Deviation Management and CAPA training course. For more information see www.gmp-compliance.org/ or send an e-mail to w.schmitt@concept-heidelberg.de.

Social Event

On 28 October, you are cordially invited to a social event (including dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

Energy Kristina Hansen
MilCor Consulting, Denmark
Senior QA Specialist

Energy Kristina Hansen has over 25 years in experience in quality assurance and compliance, spanning across food, health, manufacturing, pharmaceutical, and government sectors and works with different industry leaders to help them find the true root cause to behavior related deviations. Energy Kristina is also Guest Lecturer at the University of Copenhagen.

Cecilie Hejlskov
Syntese A/S, Denmark
Operational Excellence Manager

Cecilie Hejlskov is Operational Excellence Manager at Syntese (a Ferring company). Before that she was Specialist in Global Operational Excellence at Xellia Pharmaceuticals. Cecilie also has a Lean Six Sigma Green Belt Certification.

Tim Ohlrich
Gempex, Germany
Principal Consultant & Manager

Tim Ohlrich is an engineer in biotechnology and has been working in the GMP-regulated environment for more than 15 years. Since his start in consulting he has executed and led several GMP-compliance projects, from ATMP start-ups to global market leaders.

Wolfgang Schmitt
Concept Heidelberg, Germany
Vice President

Wolfgang Schmitt is Vice President and organises and conducts courses and conferences on behalf of the ECA Academy in the areas QA and GMP. Before that, Wolfgang was Associate Director, QP and GMP-Auditor at Abbott.

This Training Course is recognized for the
Quality Assurance Manager Certification Scheme

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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GERMANY

Reservation Form (Please complete in full)

Root Cause Analysis | 28/29 October 2025, Hamburg

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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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
Tuesday, 28 October 2025, 09.00 – 17.45 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 29 October 2025, 08.30 – 15.30 h

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

Fees (per delegate, plus VAT)
ECA Members EUR 1,890
APIC Members EUR 1,990
Non-ECA Members EUR 2,090
EU GMP Inspectorates EUR 1,045
The conference fee is payable in advance after receipt of invoice and includes 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 – or search and register directly at www.gmp-compliance.org under the number 21877.

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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