ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

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Root Cause Analysis

A CAPA Workshop on Successful Failure Investigation

13/14 December 2023 | Berlin, Germany

Highlights

- Regulations and Background
- Human Error
- Tools presented in interactive Sessions:
  - 5 Whys
  - Ishikawa (Fishbone)
  - Comparative Analyses
  - Interacting Methods
  - 3B Method (Behavioural Root Cause Analysis Tool)
- RCA Completion and Documentation

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 is it 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.

Programme

Root Cause Analysis - why is it so important?

- Regulatory background
- Examples on inspection findings and what to learn from them
- Why is it so important?
- What to do if a root cause cannot be found?

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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 Analyses

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

Presentation and Workshop: Interacting Methods

- Walk Through Analysis
- Interview
- Go See

When it's human

- Expectations on Humans
- Why human error could not be a root cause
- Blame culture vs. Root Cause
- Error Culture

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

bRCA for Human Error Related Deviations (HErD)

- Behavioural Root Cause Analysis Tool (3BMethod)
- Theory behind 3BMethod
  - 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

Social Event

On 13 December 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.

Atiq Bawary
Byondis, Netherlands
Quality Assurance Officer

Atiqullah Bawary is a Quality Assurance Officer at Byondis, a biopharmaceutical research and development company. Before his current position, he worked as a Quality Assurance Officer for a couple of years at MSD and Abbott.

Energy Kristina Hansen
Ferring, Denmark
Associate Director

Energy Kristina Hansen is a certified quality auditor (GMP/GDP/ISO), currently working for Ferring. As a consultant with her own company MilCor Consulting, she also gives courses, presentations, and lectures related to improving employee behaviour within the workplace.

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 he was Associate Director, QP and GMP-Auditor at Abbott.

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
Quality Assurance Manager Certification Scheme

Building on your education the ECA GMP/GDP certific grammes 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 | 13/14 December 2023, Berlin, 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)

Allgemeine Geschäftsbedingungen
Bei einer Stornierung der Teilnahme an der Veranstaltung berechnen wir folgende Bearbeitungsgebühr:
- Bis 4 Wochen vor Veranstaltungsbeginn 10% der Teilnahmegebühr.
- Bis 3 Wochen vor Veranstaltungsbeginn 25 % der Teilnahmegebühr.
- Bis 2 Wochen vor Veranstaltungsbeginn 50 % der Teilnahmegebühr.
- Innerhalb 2 Wochen vor Veranstaltungsbeginn 100 % der Teilnahmegebühr.

Selbstverständlich akzeptieren wir ohne zusätzliche Kosten einen Ersatzteilnehmer. Der Veranstalter behält sich Themen- sowie Referentenänderungen vor. Muss die Veranstaltung seitens des Veranstalters aus organisatorischen oder sonstigen Gründen abgesagt werden, wird die Teilnehmergebühr in voller Höhe erstattet.
Zahlungsbedingungen: Zahlbar ohne Abzug innerhalb von 10 Tagen nach Erhalt der Rechnung.

Bitte beachten Sie: Dies ist eine verbindliche Anmeldung. Stornierungen bedürfen der Schriftform. Die Stornogebühren richten sich nach dem Eingang der Stornierung. Im Falle des Nicht-Erscheinens auf der Veranstaltung ohne vorherige schriftliche Information werden die vollen Seminargebühren fällig. Die Teilnahmeberechtigung erfolgt nach Eingang der Zahlung. Der Zahlungseingang wird nicht bestätigt. (Stand Juli 2022)
Es gilt deutsches Recht. Gerichtsstand ist Heidelberg.

Datenschutz: Mit meiner Anmeldung erkläre ich mich einverstanden, dass Concept Heidelberg meine Daten für die Bearbeitung dieses Auftrages nutzt und mir dazu alle relevanten Informationen übersendet. Ausschließlich zu Informationen über diese und ähnlichen Leistungen wird mich Concept Heidelberg per Email und Post kontaktieren. Meine Daten werden nicht an Dritte weitergegeben (siehe auch Datenschutzbestimmungen unter www.gmp-navigator.com/nav_datenschutz.html). Ich kann jederzeit eine Änderung oder Löschung meiner gespeicherten Daten veranlassen.

Date
Wednesday, 13 December 2023, 09.00 – 18.00 h
(Registration and coffee 08.30 – 9.00 h)
Thursday, 14 December 2023, 08.30 – 15.30 h

Venue
HYPERION Hotel Berlin
Prager Straße 12
10779 Berlin
Germany
Tel.: +49 (0) 30/ 236250 0
E-Mail: hyperion.berlin@h-hotels.com

Fees (per delegate, plus VAT)
ECA Members EUR 1.690.-
APIC Members EUR 1.790.- (does not include ECA Membership)
Non-ECA Members EUR 1.890.-
EU GMP Inspectorates EUR 945.-
The conference fee is payable in advance after receipt of invoice and includes 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.

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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