GMP-Webinar Series on Deviation Management & CAPA

- Regulatory Background, Principles, Expectations of the Inspectorates: 12 May 2020, 14.30h CEST
- CAPA Effectiveness & System Performance Check: 13 May 2020, 14.30h CEST
- System Implementation and Human Error: 19 May 2020, 14.30h CEST
- Root Cause Analysis: 20 May 2020, 14.30h CEST

ECA Academy
Your GMP/GDP Information Source

GMP-Webinar Series on Deviation Management & CAPA

Root Cause Analysis

Date:
Wednesday, 20 May 2020, 14.30 – 16.00 h CEST

Speaker:
Michael Hopper, GxPpro

ECA has entrusted CONCEPT HEIDELBERG with the organisation of this webinar.

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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.

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.

ECA has now set up a series of four Webinars to discuss principles and relevant aspects to implement, improve and monitor your Deviation Management and CAPA System.

Educational Objectives

During the Webinar on Root Cause Analysis we will talk about:

- Root cause analysis tools
- Gathering facts & organising data
- Analysing data and facts
- Identifying root causes
- Identifying, implementing & monitoring CAPAs
- Scenarios with a focus on Human Error based and Non-human error based deviations

Target Audience

This series of webinars 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.
Each webinar can also be attended as single event.

Speaker

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.

Fees (plus VAT)
Single participation: € 199.- for ECA Members
Single participation: € 249,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at https://www.gmp-compliance.org/about-the-academy).

Participation of a Group
You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):
3-10 Persons EUR 211,15
11-20 Persons EUR 186,75
more than 20 Persons EUR 161,85

Registration
By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Technical Requirements
For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Presentation/Certificate
The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact
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Do you have any questions?
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Registration for the GMP Webinar "Root Cause Analysis"
on Wednesday, 20 May 2020, 14.30 – 16.00 h CEST
Speaker: Michael Hopper, GxPpro
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
☐ **Group Participation**
  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important: Deadline is 12 noon on 19 May 2020

Title, First Name, Last Name

Company | Department | VAT ID No. (mandatory)

Street | Postal Code/City

Phone | Fax

E-Mail (mandatory for your registration)

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 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week 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.
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)!
German law shall apply. Court of jurisdiction is Heidelberg.