



GMP Webinar

Deviations and CAPA Management - What to do and how to do

Date:

Thursday, 13 December 2018, 15.00 – 16.30 h

Speaker:

Dr Wolfgang Schumacher

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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de



GMP Webinar Deviations and CAPA Management

Background

The Pharmaceutical Quality System (PQS) requires the pharmaceutical entrepreneur to have a number of essential elements in place. Among those the deviation and CAPA (Corrective & Preventive Actions) processes play a major role: It is the expectation of Health Authority Inspectors that after each "event" the deviation management process is initiated. The trigger for deviations is usually located in the operational areas, e.g. production and control lab. Further origins may be observations during inspections, findings from internal audits, or OOSs. In many cases the deviation will initiate the generation of an entry in the CAPA system, which has to be correctly processed to avoid recurrence. If an investigation has to be started after the initial event then there are clear expectations for the independent investigator. A number of tools (checklists, investigation sheets, etc.) should be at the investigator's disposal to enable compliant reporting or - in some cases - to ensure timely information of the Health Regulatory Bodies. Despite numerous citations in Warning Letters people in charge are often confused about the requirements for these processes and in particular about their practical implementation in the company.

Educational Objectives

The Webinar aims to focus on the critical elements of the Deviation and CAPA processes and on the implementation in the field:

- Regulatory requirements
- Error vs. deviation – process comments
- Classification of deviations
- Impact assessment and Root Cause Analysis (RCA)
- The Investigation process
- Corrective measures
- Reporting
- Efficiency assessment
- CAPA – Process (Roles & Responsibilities – Workflow)

Target Audience

The participants of this Webinar should be collaborators from QC, QA and production, who are dealing with deviations and the CAPA process in the GMP area.

Speaker



Dr Wolfgang Schumacher

Dr Wolfgang Schumacher worked for ASTA Medica and F. Hoffmann-La Roche and has more than 30 years of experience in the Pharmaceutical Industry. After a successful career in Cancer Research he focused on the management of national and FDA inspections, auditing

of contract manufacturers and the accountability as QP. At Roche he established the IT quality assurance department and was recently accountable in Technical Operations as Vice Director for the GMP/CSV compliance of all global computer systems and the setup of the Data Integrity program, for Genentech as well.

Fees (plus VAT)

Single participation: € 149.- for ECA Members

Single participation: € 199.- for non-ECA Members

(This fee does not include the ECA Membership. You will find more about the ECA Membership at

http://www.gmp-compliance.org/eca_about.html.

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. **Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, schopka@concept-heidelberg.de** for details.

Group Participation (fee per person):

3-10 Persons € 169,15

11-20 Persons € 149,25

more than 20 Persons € 129,35

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.

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.

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.

Do you have any questions?

For questions regarding content please contact Mr Gerhard Becker, phone +49 62 21 - 84 44 65, E-Mail: becker@concept-heidelberg.de

For questions regarding technical aspects please contact Mr Rouwen Schopka, phone +49 62 21 - 84 44 13 email: schopka@concept-heidelberg.de

Registration for the GMP-Webinar: Deviations and CAPA Management on Thursday, 13 December 2018, 15.00 – 16.30 h CET
Speaker: Dr Wolfgang Schumacher
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
12 December**

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!)