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GMP Webinar *Recording*

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

Date of the recording: 13 December 2018

Speaker: Dr Wolfgang Schumacher

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

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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: € 199.- for ECA Members
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Do you have any questions?
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Registration for the Webinar *Recording*: **Deviations and CAPA Management of 13 December 2018, Speaker: Dr Wolfgang Schumacher**
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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