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GMP Webinar *Recording*
Audit Trail Review

Date of the recording: 16 February 2017

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 *Recording:* **Audit Trail Review**

Background
The topic "data integrity" is at present one of the major focal points in national and international Health Authority inspections. The American FDA has found a significant number of deviations which were reported in warning letters in the last years. In addition to the assurance of product quality the authorities require from all companies a clear strategy how the integrity of critical data can be ensured over their entire lifecycle. The Review of Audit Trails plays a key role in this respect. Despite the various guidelines which were published after 2015 there is no clarity about the requirements for Audit Trail review and how it can be implemented in the daily business.

Educational Objectives
The Webinar aims to focus on the critical elements of data integrity and Audit Trail Review:

- Regulatory Overview with emphasis on the requirements of MHRA and Annex 11
- Classification of data – which are critical data?
- Classification of systems – which systems are relevant?
- What Audit Trails are of importance?
- What shall I do with legacy systems without Audit Trail?
- Who shall review Audit Trails?
- How is it documented?
- What process and documentation is appropriate in case of deviations?

Target Audience
The audience of this Webinar should be collaborators from QC, QA, production and IT, which are dealing with data integrity and the review of Audit Trails, are engaged as system administrators or manage computer systems 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 www.gmp-compliance.org/eca_about.html.)

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Registration
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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:
Dr Günter Brendelberger, phone +49 62 21 - 84 44 40,
E-Mail: brendelberger@concept-heidelberg.de.
For questions regarding technical aspects:
Ronny Strohwald unter Telefon 06221-84 44 51,
E-Mail: strohwald@concept-heidelberg.de.

Registration for the GMP Webinar *Recording*: **Audit Trail Review of 16 February 2017**
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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