ECA Academy
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GMP Webinar
Audit Trail Review

Update 2019

How to comply with the latest Guidelines in practice

Date:
Wednesday, 6 March 2019, 15.00 – 16.30 h CET

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

Background
"Data Integrity" is still one of the major topics during inspections by the American FDA and European health regulatory bodies. Last year a number of guidelines were published in their final versions; therefore, it was expected that the subject "Audit Trail Review" was clarified and can be considered as resolved. Unfortunately, despite these new guidelines, the implementation of a compliant and manageable audit trail review in the pharmaceutical industry is not well defined, in particular for companies exporting products to foreign markets. The requirements of the FDA are - to some extent - in contrast to those of European authorities. In this respect the PIC/S document 041, which was published in its draft version 3 at the end of 2018, created more confusion than clarity, e.g. for the management of scanned documents.

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 FDA, PIC/S 041, Annex 11 und MHRA
- New requirements in PIC/S 041
- Classification of data – which are critical data?
- What Audit Trails are of importance in production and QC/QA??
- Who shall review Audit Trails?
- How is the review 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.)

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

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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:
Dr Günter Brendelberger, phone +49 62 21 - 84 44 40,
E-Mail: brendelberger@concept-heidelberg.de.
For questions regarding technical aspects:
Mr Rouwen Schopka
E-Mail: schopka@concept-heidelberg.de.

Registration for the GMP-Webinar: Audit Trail Review - Update 2019
Wednesday, 6 March 2019, 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**
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  ☐ 3-10 Persons
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  ☐ more than 20 Persons

Important: Deadline is 12 noon on 5 March 2019

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