ECA Academy
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GMP Webinar
Audit Trail Review

Date:
Thursday, 16 February 2017, 15.00 – 16.30 h CET

Speaker:
Dr Wolfgang Schumacher

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

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GMP-Webinar 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.)

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
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http://www.gmp-compliance.org/webinar/webinar_requirements.htm

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:
Ronny Strohwald unter Telefon 06221-84 44 51,
E-Mail: strohwald@concept-heidelberg.de.

Registration for the GMP-Webinar: Audit Trail Review
Thursday, 16 February 2017, 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 15 February 2017

Title, First Name, Last Name

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E-Mail (mandatory for your registration)

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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 %.
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