
ECA Academy
Your GMP/GDP Information Source

# GMP Webinar
# **Audit Trail Review - Update 2018**

Date:
Wednesday, 14 February 2018, 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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**Background**
The topic "data integrity" is at present one of the major focal points in national and international Health Authority inspections. The pharmaceutical industry has already started to implement measures in Quality Control and the Quality Unit to ensure the integrity of data for the paper based documentation and the computerized systems. Recently, the Health Regulatory Bodies have started to check more frequently systems in the manufacturing, the quality control area and in the clinical sector . In these inspections emphasis is made particularly on data and parameters that could influence the patient safety. The topic "audit trail review" continues to lack a comprehensive definition in the guidelines; therefore many companies are investing more capacity in the routine control of audit trails than requested by law.

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

- Regulatory Overview – Update 2018
- Manufacturing and QC data – which are critical data?
- Data Integrity in the GCP area
- 4-eyes-principle vs. second person review – What makes sense?
- Classification of systems – Which systems are relevant?
- Who should review audit trails? – QA?
- 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, clinical research/monitoring and IT, which are dealing with data integrity and the review of Audit Trails, are engaged as system administrators or manage/monitor computer systems in the GMP and GCP 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**
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. You will find the detailed system requirements here:
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:
Mr Rouwen Schopka
E-Mail: schopka@concept-heidelberg.de.

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**Registration for the GMP-Webinar: Audit Trail Review - Update 2018**
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**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 13 February 2018**

Title, First Name, Last Name

Company | Department | VAT ID No. (mandatory)

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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 %.
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