
ECA Academy
Your GMP/GDP Information Source

# GMP Webinar
# **Data Integrity – An Update**

Date:
Tuesday, 11 April 2017, 15.00 – 16.30 h CEST

Speaker:
Dr Wolfgang Schumacher


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

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# GMP-Webinar Data Integrity – An Update

**Background:**
The integrity of data is one of the key principles of GMP which got lots of attention by the Health Regulatory Bodies in the past three years. The large number of FDA Warning Letters and Non-Compliance Reports created by the EMA are an indication for the existing compliance issues which are reported for all countries.
As a reaction on the problems discovered, the Regulators started to define their requirements for the data life cycle and expectations how they should be met by the pharmaceutical industry. A real "Tsunami" of drafts of Guidelines and Guidances (FDA / PICS / MHRA / WHO) was coming up creating lots of uncertainness on the industry side.

**Educational Objectives:**
The Webinar aims to focus on presenting the data integrity developments of the past two years and evaluate their impact on the industry. A number of first-line activities to establish a data integrity strategy will be presented; the discussion will also highlight actions in case of DI issues:

- Introduction – The Data Integrity Hype
- Regulatory update – What's new? / Highlights
  - PIC/S / FDA / Annex 11 Revision
  - How to deal with copies and scans?
  - Static / Dynamic Data
  - Testfolders
- Recent regulatory observations – from lab to production
- The data integrity strategy
  - Prioritization of systems and risks
  - Initial management activities – policy / strategy / training
  - Initial IT activities – administrator / annotation function
- How to deal with data integrity problems
  - Management of health authorities
  - CAPA
  - Internal recording and documentation
  - HR measures

**Target Audience:** The audience of this Webinar should be collaborators from QC, QA, production and IT, which are dealing with data integrity, are engaged as system administrators or manage computer systems in the GMP area.

**Speaker**

**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 Andreas Mangel, phone +49 62 21 - 84 44 41,
email: mangel@concept-heidelberg.de.

For questions regarding technical aspects:
Mr Rouwen Schopka, phone +49 62 21 - 84 44 13
email: schopka@concept-heidelberg.de

**Registration for the GMP-Webinar: Data Integrity – An Update**
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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 10 April 2017**

Title, First Name, Last Name

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**General Terms and Conditions**
If you cannot attend the conference you have two options:
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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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