



GxP Webinar

Data Integrity from the view of a GMDP Inspector

Date:

Monday, 5 October 2020, 14.00 - 16.00 h CEST

Speaker:

Dr Franz Schönfeld, District Government of Upper Franconia

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

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Background

Data Integrity is still a major concern with both the FDA and European Regulatory Agencies. Many FDA warning letters and EU GMP inspections have highlighted major data integrity failures at companies worldwide.

Data integrity is not a new topic: The principles apply to electronic and to paper-based systems. Major topics cover

- IT Security, System and Data Integrity
- Written Policies
- Data Life Cycles
- Principles of ALCOA+
- Handling of Raw Data
- Review of Data

As electronic data is widespread in Quality Control but also in Production it is getting more and more interest of GMDP inspectors.

Educational Objectives

Major objectives of this webinar are as follows:

- Basic Regulatory Requirements
- IT Security and User Management
- Handling of Data (including Raw Data)
- Data Integrity
- Examples (Production and Quality Control)
- Inspection Findings

Target Audience

This webinar is addressed to employees of pharmaceutical manufacturers, authorities and suppliers with responsibility in

- Quality assurance
- Production
- Quality Control
- Inspections and audits

Speaker



Dr. Franz Schönfeld

District Government of Upper Franconia

Dr Franz Schönfeld is currently a GMP and GDP inspector with the government of Upper Franconia. He is also head of the Expert Group (EFG) 7 for Active Pharmaceutical Ingredients and Excipients at the Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) and member of the GMDP Inspectors Working Group at the European Medicines Agency (EMA) in Amsterdam. He also holds a teaching position at the University of Erlangen-Nuremberg.

Fees (plus VAT)

Single participation: € 199,- for ECA Members

Single participation: € 249,- for non-ECA Members

(This fee does not include the ECA Membership. You will find more about the ECA Membership at <https://www.gmp-compliance.org/about-the-academy>).

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.

Group Participation (fee per person):

3-10 Persons € 211,65

11-20 Persons € 186,75

more than 20 Persons € 161,85

Registration

By mail, fax, e-mail or online on the Internet at <https://www.gmp-compliance.org>. 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.

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 plugin. 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.

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.

Organisation/Contact

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Do you have any questions?

For questions regarding content please contact:

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For questions regarding technical/organisational aspects please contact:

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Registration for the GxP Webinar

"Data Integrity from the view of a GMDP Inspector"

on Monday, 5 October 2020, 14.00 – 16.00 h CEST

Speaker: Dr Franz Schönfeld

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

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more than 20 Persons

**Important:
Deadline is 09.00 h CEST on
5 October 2020**

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

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Fax

E-Mail (mandatory for your registration)

General Terms and Conditions

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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will

receive a full refund of fees paid.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance.

If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed!)