



# GxP Webinar

## Data Integrity Strategies

Date:

Tuesday, July 21st 2020, 14.00 – 16.00 h CEST

Speaker:

Dr Wolfgang Schumacher, formerly F. Hoffmann-La Roche

**Participants receive an example of a DI Policy and the corresponding DI SOP**

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

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## Background

In the past, in particular larger companies were requested by the authorities to take appropriate measures for ensuring Data Integrity. However, inspectors are now also asking small and medium-sized pharmaceutical facilities to present all DI elements during an inspection, mainly in QC and production. In this context it will be not sufficient to show only high-level documents (DI policy, DI SOP); rather, they are demanding to disclose a well-defined strategy, in which all measures including CAPAs together with a timetable are included. The webinar will present pragmatic approaches to how data integrity can be defined, maintained and presented in a smaller company without excessive additional financial outlay. The speaker will also highlight some of the topics and issues that may be addressed during an inspection, in particular:

- Structure of the data integrity program
  - Which documents are primarily required?
  - Prioritization of activities
  - Required capacity, timetable
- Data Governance
  - Responsibility of the management
- Training
- CAPA
- Actions in case of data integrity problems

## Learning Objectives

The aim of the webinar is to provide answers to the following questions for practical application:

- Which is the optimal form to present DI remediation measures?
- Documentation of the strategy
- Involvement of the management
- Activities in laboratory and production facilities
- Audit Trail Review - is that really necessary?

## Target Audience

The event is aimed at managers and employees of pharmaceutical and medical technology companies who have to implement the current requirements for data integrity in their premises in an inspection-proof manner.

## Course Material

Participants receive an example of a DI Policy and the corresponding DI SOP.

## Speaker



**Dr Wolfgang Schumacher, formerly F. Hoffmann-La Roche**  
35 years of experience in the field of Quality Assurance, CSV, Data Integrity and health regulatory inspections, most recently 17 years in global leading positions with F. Hoffmann-La Roche in Basel. He is Chairman of the IT Compliance Group of the ECA.

## 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 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.

## 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:  
Ms Marion Grimm, phone +49(0)6221 / 84 44 18  
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## Registration for the GxP Webinar "Data Integrity Strategies" on Tuesday, 21 July 2020, 14:00 – 16:00 h CEST

Speaker: Dr Wolfgang Schumacher

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at [www.gmp-compliance.org](http://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  
20 July 2020**

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

Street

Postal Code/City

Phone

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!)