



# GxP Webinar

## Preparation for a Data Integrity Inspection

Date:

Monday, 6 July, 2020, 14.00 -16.00 h CEST

Speaker:

Dr Wolfgang Schumacher, formerly F. Hoffmann-La Roche

**The participants will receive an Excel sheet including the corresponding check/question list to assess the Data Integrity risk of their electronic systems**

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

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## Background

During an inspection by the local or international Health Regulatory Bodies, all organisational and technical measures taken to ensure data integrity in the company must be demonstrated. It is necessary to show a clear structure of these activities together with the internal controls established, for example by QA. All measures should be planned on a risk-based basis, i.e. taking into account the risk for the product, the process and the patient; pragmatic approaches will help to keep the additional costs incurred under control.

The webinar will emphasize on many of the issues that could be addressed during an inspection and provide participants with appropriate solutions to ensure a successful inspection. Important topics are in particular:

- Inventory of the Systems
- Analysis of the DI Status / GAP Assessment / Data Governance
- Risk Assessment / Action Plan
- What do the Inspectors Want to See - Overview
  - Audit Trail Review
  - Stand-Alone Systems
  - CAPAs
- Inspection Observations

## Learning Objectives

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

- What is the Best Way to Present DI Measures Taken?
- Risk-based Assessment Approach
- Involvement of the Management
- Audit Trail Review
- Inspection Observations of the FDA and European Authorities

## Target Audience

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

## Course Material

The participants will receive an Excel sheet including the corresponding check/question list to assess the Data Integrity risk of their electronic systems. Two numerical values will be ejected as a result: Total risk and audit trail risk.

## Speaker



**Dr Wolfgang Schumacher, formerly F. Hoffmann-La Roche, Basel**

35 years of experience in the field of GMP inspections, most recently 17 years 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 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

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,  
Tel. +49(0)6221/84 44-0, Telefax +49(0)6221/84 44 34  
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## Do you have any questions?

For questions regarding content please contact:  
Dr Andreas Mangel, phone +49(0)6221 / 84 44 41  
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For questions regarding organisational aspects please contact:  
Mr Ronny Strohwald, phone +49(0)6221 / 84 44 51  
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## Registration for the GxP Webinar "Preparation for a Data Integrity inspection"

on Monday, 6 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 09.00 h CEST  
on 6 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!)