
ECA Academy
Your GMP/GDP Information Source

# GCP Webinar
# GCP Update – Computer Validation and Data Integrity in Clinical Trials

Date:
Wednesday, 08 July 2020, 14.00 – 15.30 CEST

Speaker:
Dr Wolfgang Schumacher, Chair of ECA's Data Integrity & IT Compliance Group


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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

## Background

In **clinical trials** (CTs), large amounts of data are collected and this data is electronically recorded and processed to a growing extent. Checking **Data Integrity** (DI) is mandatory and is usually performed by the clinical monitor.
In addition, sponsors contract out an increasing number of tasks in CTs. During inspections of clinical trials, a growing number of deviations from GCP standards related to contractual arrangements with vendors of electronic systems and related procedures have been identified by the inspectors.
In order to clarify these issues, the EMA has recently published a *„Notice to sponsors on validation and qualification of computerized systems "*. In this Notice, the EMA clearly states:

- The **sponsor** is ultimately responsible for the *validation of the computerized system* (CS) and for providing adequate documented evidence,
- Failure to document the validated state of a CS is likely to pose a risk to **Data Integrity**,
- It is not acceptable to use CSs in CTs for which the validation status is not confirmed or appropriately documented

## Educational Objectives

During this Webinar you will get to know the principles of Computer Validation (CV) and Data Integrity in the light of GCP requirements.

## Programme

- New EMA GCP Computer Validation Guidance – Impact on ongoing validation projects?
- Emphasis of validation in the GCP area
- Data Integrity in clinical trials
  - CRF (**Case Record Form**)
  - ICF (**Informed Consent Form**)
- Are the EU GDPR rules applicable?
- Concerns of the Regulators – Inspection findings

## Target Audience

Employees involved in designing, conducting, evaluating, and documenting of clinical trials, like Validation manager, QA manager, project manager, data manager, and statisticians. Pharmaceutical companies, sponsors, contractors (for example CROs, analytical labs) and vendors for electronic systems (including hosting partner). Inspectors responsible for performing GCP inspections and needing to understand and assess data integrity.

## Speaker

**Dr Wolfgang Schumacher, Chair of ECA's Data Integrity and IT Compliance Group, formerly Roche, Switzerland**
Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. From 2001 to 2016 he was Head of the department of Quality Computer Systems at F. Hoffmann- La Roche, Basle. He is a member of the ECA Advisory Board.

## 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 EUR 211,65
11-20 Persons EUR 186,75
more than 20 Persons EUR 161,85

## 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.

## 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

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
info@concept-heidelberg.de, www.gmp-navigator.com

## Do you have any questions?

**For questions regarding content please contact:**
Dr Andrea Kühn-Hebecker
Phone +49(0)6221 / 84 44 35
Email: kuehn@concept-heidelberg.de

**For questions regarding organisational aspects please contact:**
Ms Sonja Geppert
Phone +49(0)6221/ 84 44 16
Email: geppert@concept-heidelberg. de.

---

**Registration for the GCP Webinar "GCP Update – Computer Validation and Data Integrity in Clinical Trials" on Wednesday 08 July 2020, 14.00 – 15.30 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.

Please tick:
☐ **Single Participation**
☐ **Group Participation**
  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

**Important: Deadline is 12 noon on 07 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)!
German law shall apply. Court of jurisdiction is Heidelberg.