



GMP Webinar

Data Integrity in the Light of ICH Q7

Date:

Thursday, 15 October 2020, 14.00 – 15.30 h CEST

Speaker:

Dr Markus Dathe, F. Hoffmann-La Roche, Basel, Switzerland

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

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Background

Data Integrity has become the major regulatory concern with Regulatory Agencies who have issued several guidance documents which focus on computerized systems, data governance and data. Even though drug products are often in the focus of Data Integrity audits and inspections, Data Integrity compliance is likewise required for Active Pharmaceutical Ingredients (APIs). The ICH Q7 guideline provides information especially for the GMP-compliant manufacturing, documentation and handling of Active Pharmaceutical Ingredients (APIs) as well as Data Integrity requirements.

Educational Objectives

This webinar will give you a comprehensive overview of the Data Integrity requirements for APIs laid down in the ICH Q7 guideline. Risk-based approaches as well as interpretations will be discussed and explained.

- Which requirements are applicable to APIs under ICH Q7?
- Specific Requirements and Interpretations
- Consideration for specific risks
- The hubris of hybrid records
- Case study: how to achieve Data Integrity on a risk-based approach

Target Audience

This webinar is designed for all persons involved in Data Integrity processes related to the manufacture and GMP-compliant documentation of APIs, especially for persons from Production, Quality Control, Quality Assurance, Technical and Regulatory Affairs departments as well as for Qualified Persons and Auditors.

Speaker



Dr Markus Dathe, F. Hoffmann-La Roche AG, Basel, Switzerland

Analytical and Process Chemist with more than 20 years of practical experience in laboratory, quality and informatics functions. Dr Dathe held several positions in life sciences and pharma operations of Novartis since 1997, joined Siegfried in 2006 and is GMP Coordinator in the Small Molecules Technical Development of Roche since 2011. He had been successfully leading global projects in the area of CDS, LIMS and QMS.

Registration for the Webinar "Data Integrity in the Light of ICH Q7" on Thursday, 15 October 2020, 14.00 – 15.30 h CEST

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Please fax to CONCEPT HEIDELBERG, +49 (0)6221/84 44 34 or you register online at www.gmp-compliance.org.

Fees (plus VAT)

Single participation: € 249,- for ECA Members

Single participation: € 299,- 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 € 254,15

11-20 Persons € 224,25

more than 20 Persons € 194,35

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 organisational aspects please contact:

Ms Sonja Geppert, phone +49(0)6221/84 44 16

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Please tick:

- Single Participation**
- Group Participation**
 - 3-10 Persons
 - 11-20 Persons
 - more than 20 Persons

Important:
Deadline is 12 noon on
14 October 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 %.

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