



# GMP Webinar

## **Data Integrity: GMP requirements and how to implement them**

Date:

Wednesday, 28 January 2015, 14.00 – 16.00 h CET

Speaker:

Yves Samson, Kereon AG, Switzerland



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

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## GMP Webinar

### Data Integrity: GMP requirements and how to implement them

#### Background

Over the last years, the regulatory pressure regarding the integrity of GxP relevant data increases significantly. Not only the US-FDA but various regional and national authorities as well investigate with increasing rigour the handling of critical and GxP data.

#### Educational Objectives

Based on several case studies, this Webinar will make you confident with both integrity criterion as well as applicable regulatory requirements and expectations. Furthermore, this Webinar will also address the organisational interfaces between regulated user and its suppliers and service providers.

- What data?
  - For which purpose?
  - Data life cycle
  - About data integrity
- Integrity criterion
- Case studies
  - Integrity traps to avoid
- Regulatory requirements / Annex 11 vs. 21 CFR 11
- Organisational interfaces
  - Data ownership and responsibilities
- 12 data integrity commandments
- Conclusion

#### Target Audience

This webinar targets in particular executives and staff working in:

- Quality units - QA and QC
- Analytical and laboratory units
- Manufacturing and process automation
- Supporting IT personnel

#### Speaker



##### Yves Samson, Kereon AG, Basel, Switzerland

Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. Within ISPE he was an active member of the working group "IT Infrastructure Compliance and Control".

#### Fees

€ 149.- plus VAT for ECA members  
€ 199.- plus VAT for non-ECA Members

#### Participation of a Group

The registration fee only authorises an individual to take part in the Webinar. Therefore, we do not issue more than one certificate per registration. With the registration fee being paid only once, it would infringe the copyright of CONCEPT HEIDELBERG as well as that of the speaker if the transmission was followed by several persons.

If you wish to register a group, please send an e-mail to [info@concept-heidelberg.de](mailto:info@concept-heidelberg.de) or contact us by phone (+49 (0)62 21 / 84 44 51 Mr Strohwald).

Prior to the Webinar date, we will help you to establish and test the Internet access.

#### Technical Requirements

To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers.

Your Internet browser must have following features to use the GMP Webinar system:

1. Adobe Flash-Player must be installed.
2. Javascript must be allowed.
3. Port 1935 must be released.

#### Registration

By mail, fax, e-mail or online on the Internet at [www.gmp-compliance.com](http://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.

#### Presentation/Certificate

The presentation will be made available to you prior to the Webinar as PDF file. After the Webinar, we will automatically send you a certificate of participation.

#### Do you have any questions?

For questions regarding content:

Dr Andreas Mangel, phone +49 62 21 - 84 44 41,  
E-Mail: [mangel@concept-heidelberg.de](mailto:mangel@concept-heidelberg.de),

For questions regarding technical aspects:

Mr Matthias Zimmermann, phone +49 62 21 - 84 44 59,  
[zimmermann@concept-heidelberg.de](mailto:zimmermann@concept-heidelberg.de).

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**Registration for the GMP Webinar Data integrity: GMP requirements and how to implement them, Wednesday, 28 January 2015, 14.00 – 16.00 h CET**

**Speaker: Yves Samson, Kereon AG, Basel, Switzerland**

**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).**

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#### 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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