GMP Webinar RECORDING
Data Integrity – An Update

Date of the recording: Tuesday, 11 April 2017
Speaker: Dr Wolfgang Schumacher
Target Audience:
The audience of this Webinar should be collaborators in the GMP area, integrity, are engaged as system administrators or manage computer systems in the GMP area.

Educational Objectives:
The Webinar aims to focus on presenting the data integrity developments of the past two years and their impact on the industry. A number of first-line activities to establish a data integrity strategy will be presented; the discussion will also highlight actions in case of DI issues:

- Introduction – The Data Integrity Hype
- Regulatory update – What’s new? / Highlights
  - PIC/S / FDA / Annex 11 Revision
  - How to deal with copies and scans?
  - Static / Dynamic Data
  - Testfolders
- Recent regulatory observations – from lab to production
- The data integrity strategy
  - Prioritization of systems and risks
  - Initial management activities – policy / strategy / training
  - Initial IT activities – administrator / annotation function
- How to deal with data integrity problems
  - Management of health authorities
  - CAPA
  - Internal recording and documentation
  - HR measures

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. You will find the detailed system requirements here:
http://www.gmp-compliance.org/webinar/webinar_requirements.htm

Registration
By mail, fax, e-mail or online on the Internet at 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.

Do you have any questions?
For questions regarding content:
Dr Andreas Mangel, phone +49 62 21 - 84 44 41, email: mangel@concept-heidelberg.de.
For questions regarding technical aspects:
Mr Rouwen Schopka, phone +49 62 21 - 84 44 13 email: schopka@concept-heidelberg.de

Registration for the Webinar Recording: Data Integrity – An Update of 11 April 2017, Speaker: Dr Wolfgang Schumacher
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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