ECA Academy
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GMP Webinar
Analytical Instrument Qualification: GAMP Regulations for Computer System Validation & Data Integrity

Date:
Tuesday, 15 June 2021, 15.30 - 17.00 h CEST

Speaker:
Dr Karl-Heinz Bauer, Boehringer Ingelheim International GmbH, Germany

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 QC laboratories, there is a large number of analytical devices that need to be qualified according to GMP regulations and shall be kept in a qualified status over the entire life-cycle of the device. Smoothly running device functions strongly depend on error-free software features. The decision for a validation concept or a process model has far-reaching consequences, especially for the meaningfulness of the suitability of the software and device and the validity of its desired purpose as well as for the testing and documentation efforts. Special attention is paid to Data Integrity of the generated data.

Educational Objectives
This webinar provides you with basic information about software validation concepts and shows you how to proceed using selected practical examples. The principles for Data Integrity, for different software functions/types and for supplier involvement within the framework of the computer system validation are specifically addressed.

Computerized Systems & Devices (Introduction into CSV)
- GAMP Guidelines for Computerized System in QC Laboratories in a nutshell
- Reference to USP <1058> Analytical Instrument Qualification
- Terms and Definitions
- Software categories according to GAMP 5 Guidelines
- Core elements of a holistic CSV approach
- Life cycle concept / The V-model
- Software features and types
- Functional specifications and requirements
- Measures to maintain a valid Computerized System throughout its entire Life-Cycle
- Data Integrity (ALCOA), Data Security, System Modification, Incident and Emergency Management
- Supplier participation and collaboration

Target Audience
This webinar is designed for employees from analytics, quality control, engineering and quality assurance who are responsible for device qualification or with device operation responsibilities. In addition to employees of pharmaceutical companies and external laboratories, employees of service providers in the areas of qualification / validation are also addressed.

Speaker

Dr Karl-Heinz Bauer, Boehringer Ingelheim International GmbH, Ingelheim, Germany
Dr Bauer holds a PhD in pharmaceutical engineering and has been with Boehringer Ingelheim for more than 25 years. He has held various senior management positions in quality assurance, quality control and pharmaceutical manufacturing. During this time, he was also responsible for a lab engineering group responsible for qualification and validation of lab devices as well as for a QA group responsible for the Computer System Validation Management at Boehringer Ingelheim Germany. Since January 2020, he has taken over a strategic, international quality management position. In addition to that, Dr Bauer works now for many years as a speaker, consultant and coach in the pharmaceutical industry.

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
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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:
Ms Anne Günster, phone +49(0)6221 / 84 44 50
Email: guenster@concept-heidelberg.de

For questions regarding organisational aspects please contact:
Mr Niklaus Thiel, phone +49(0)6221 / 84 44 43
Email: thiel@concept-heidelberg.de

Registration for the GMP Webinar: Analytical Instrument Qualification: GAMP Regulations for Computer System Validation & Data Integrity on Tuesday, 15 June 2021, 15.30 - 17.00 h, Speaker: Dr Karl-Heinz Bauer, Boehringer Ingelheim International GmbH, Germany
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
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Important: Deadline is 12.00 am on 14 June 2021

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