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GMP Webinar
Data Integrity in Qualification and Validation Documentation

Date:
Thursday, 21 January 2021, 14.00 -15.30 h (CET)

Speaker:
Dr Rainer Gnibl, GMP Inspector, Local Government of Upper Bavaria

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

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Background
The topic documentation and - directly linked to it - the topic data integrity are not new. Since the EU GMP Guide came into force in 1992, there has been a own chapter about documentation. Also Annex 11 regarding computerised systems has been valid since then. Part II of the EU GMP Guide (GMP for APIs) also contains requirements regarding documentation and data integrity. With the revision of chapter 4 on documentation in 2011, a new sub-chapter about Good Documentation Practice was added. Annex 11 was also revised in 2011. Requirements for the qualification and validation documentation are mentioned in Annex 15 and in the FDA Guidance on Process Validation. The rules are in principle very simple: it is all about traceability.. In the last years, deficiencies, either accidental or deliberate have been occurring. What are the requirements in terms of data integrity in qualification and validation documentation, especially with the integration of external documents from suppliers and external services? Get first hand information from a GMP inspector.

Educational Objectives
From an inspector´s view, the following issues will be addressed:
- What documentation is needed during qualification and validation?
  - Protocol vs record vs report
  - What areas are critical?
  - Who is responsible for qualification and validation documentation?
- Basic requirements for a GMP compliant (?) documentation
  - Good Documentation Practice
- GMP-compliant Data integrity – what is that?
  - ALCOA
  - ALCOA Plus
- Implementation of suppliers – what is important?
  - Electronic documentation from a supplier – how to handle and to archive in accordance with GMP
  - Entries from service providers – the devil is in the detail
- Case studies from GMP inspections
  - What is the inspector looking for? Oder eher What does the inspector pay attention to?

Target Audience
Employees from companies, who are involved in qualification and process validation activities (heads of production, heads of validation group, developers, QM, etc.) are addressed. Also suppliers and service providers who deliver qualification and validation documentation or make entries in these documents are also addressed as well as consultants in this field.

Speaker

Dr Rainer Gnibl, GMP Inspector, Local Government of Upper Bavaria
Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP-inspections worldwide. Rainer Gnibl is head of the nationwide expert group EFG2 "GMP Inspection" and is responsible for "Third Country Inspections" at the Government of Upper Bavaria Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

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
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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
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Do you have any questions?
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Registration for the Webinar: "Data Integrity in Qualification and Validation Documentation" on Thursday, 21 January 2021, 14.00 -15.30 h (CET)
Speaker: Dr Rainer Gnibl
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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Important: Deadline is 12 noon on 20 January 2020

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