ECA Academy
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GMP Webinar
Auditing of Data Integrity
Approaches and Tips

Date:
Thursday, 5 September 2019, 14.00 - 15.30 h CEST

Speaker:
Dr Thierry Dietrich

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

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Background

The auditing and assessment of data integrity is getting more and more relevant. This includes its coverage in authority inspections, external and internal audits, self-assessments and other type of assessments. Auditing and assessing data integrity is of paramount importance within the quality risk management of any life sciences company's quality system.

There are many reasons for the growing relevance of data integrity, even though it is no new requirement. Some of them are:

- the increasing usage of electronic records and signatures across the pharmaceutical and medical devices industry
- the ever growing complexity of the IT landscape
- the implementation of new technologies (e. g., Cloud Computing, Blockchain, Track & Trace, IoT)
- the associated growing focus on data integrity in public authority inspections in the last years
- evolving regulatory requirements and guidance as well as standards in technology

However, economic activities such as headcount reduction, efficiency and productivity optimization, outsourcing of processes and activities, growing complexity in the supply chain, etc. lead to an increasing importance of data integrity audit programs as well, as these can have a serious impact on data integrity.

Educationasl Objectives

The goal of this Webinar is to provide answers to the following questions:

- What are typical inspection findings pertaining to data integrity?
- What are the expectations/requirements of public authorities towards the auditing of data integrity?
- How do I integrate data integrity into my audit planning?
- Which measures can be taken during audit preparation?
- Which approaches exist during audit execution to delve into this topic?
- How do public authorities approach data integrity in their inspections?

Target Audience

The Webinar targets responsible individuals in quality assurance, quality control, audit departments, production and IT as well as other relevant departments being subject to inspections or audits, or auditing / assessing data integrity themselves.

Speaker

Dr Thierry Dietrich serves in leading and consulting positions within the pharmaceutical and medical devices industries for more than 20 years. He founded pharm@dviser in 2016, and acts as management consultant. His areas of focus are data integrity auditing, auditing of IT suppliers and IT organizations, leading of large IT projects in GxP regulated areas, validation of computerized systems, as well as the building and optimization of quality management systems with focus on IT and data quality. Thierry Dietrich was/is leader resp. member of several GAMP® SIGs and ISPE. He also is the author of numerous technical publications, and speaker on technical conferences.

Fees (plus VAT)
Single participation: € 149.- for ECA Members
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http://www.gmp-compliance.org/eca_about.html.

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. **Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, schopka@concept-heidelberg.de** for details.

Group Participation (fee per person):
3-10 Persons € 169,15
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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 GMP Webinar: Auditing of Data Integrity Approaches and Tips on Thursday, 5 September 2019, 14.00 - 15.30 h CEST
Speaker: Dr Thierry Dietrich
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 4 September 2019

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