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GMP Webinar
CSA – Computer Software Assurance

Date:
Wednesday, 24 August 2022, 14.00 – 16.00 h (CEST)

Speaker:
Marc Kötter, Fresenius Medical Care
Founding member of the so-called FDA-Industry CSA Team (FICSA)

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

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Background
Although risk-based software validation is already a best practice, many life science companies are still reluctant to reduce validation activities and/or documentation using risk-based decisions. One reason for this is that the relevant software validation regulations are very general and companies

- either do not know exactly how they should be interpreted
- or they fear that the authorities may have a different interpretation/ expectation.

The result is that these companies either do not take a risk-based approach at all or, more often, despite taking a risk-based approach, still focus primarily on extensive validation documentation rather than on risk to the patient or product quality, as well as the software quality itself.

A group of life science industry representatives has teamed up with the FDA to launch an initiative to promote a risk-based approach that focuses more on software quality while significantly reduces the documentation burden. The result is what is called Computer Software Assurance (CSA), for which the FDA will publish a related guidance document (Guidance for Industry).

In this webinar, you will learn first-hand what CSA is all about from **one of the founders of the so-called FDA-Industry CSA Team (FICSA)**, which created CSA and produced the associated guidance document. You will learn how to integrate CSA ideas into existing validation processes, why you should do so, and what benefits you can expect.

Educational Objectives
The objective of this webinar is to provide answers to the following questions:

- What is CSA all about, what are the differences to CSV?
- What is the added value of CSA?
- Is CSA compliant with all laws and regulations?
- What can be done to consider CSA in software validation?

The following details will be covered:

- CSA Introduction:
  - Key aspects of CSA
  - CSA vs. CSV (comparison with existing software validation guidelines and best practices such as GAMP5).
- How to consider CSA when validating software:
  - Effectively address the risk-based approach
  - Reduce the burden of validation documentation
  - Use of alternative test documentation methods
  - Use of software QA activities that have already been performed prior to validation (keyword: vendor testing)
- Examples:
  - A common document for user requirements, risk and test management, and traceability
  - Different types of test documentation
  - Real project benefits

Target Audience
The webinar is aimed at employees from the pharmaceutical industry and suppliers who are currently and, in the future, involved in the topic of CSA in the IT environment.

Speaker

Marc Kötter, Fresenius Medical Care
Has worked for Fresenius Medical Care for 10 years and is the global process owner for all IT quality assurance processes there. He is responsible for and oversees all global software validation activities of the company. Marc is a founding member of the FDA Industry CSA Team (FICSA), which created CSA and produced the draft FDA Guidance for Industry: Computer Software Assurance (CSA) for Manufacturing, Operations, and Quality System Software, which will be published soon.

Fees (plus VAT)
Single participation: € 249.- for ECA Members
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(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 EUR 254,15
11-20 Persons EUR 224,25
more than 20 Persons EUR 194,35

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

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