



GxP Webinar

Audits / Inspections of Computerised Systems - Gaining Practical Insights

Trust is good, control is better? – controlled control!

Date:

Wednesday, 22 July 2020, 14.00 - 16.00 h CEST

Speaker:

Dr Timo Kretzschmar, anapur AG Region Wien



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

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Background

Computerised systems have continuously developed over the years as an "omnipresent companion" in the GxP landscape. It is not a "clearly representable" area, but an inherent dimension in the entire GxP with a rapidly growing influence on drug safety.

As practical difficulties in the classification and treatment of computerised systems reveal, they are sometimes difficult to "separate" from their environment, can only be grasped in their entirety and thus be identified as GxP-relevant in the given case.

Computerised systems include a wide variety of forms of appearance, e.g.:

- Excel spreadsheets (with formulas)
- Production-supporting software without sensors / actuators via (individual) controls of production equipment
- complex process control systems
- broadly based cloud systems of global organisations

In order to use resources carefully, it is advisable to use audits to illuminate this jungle of possibilities with the „glasses of compliance“ before actions are taken.

The focus of this webinar is on the target-oriented use of audits to achieve compliance with legal and operational requirements. This works best accompanied by the practical, continuous improvement and development of the ability to distinguish the necessary from cosmetic issues. This prevents audits from becoming formal activities.

Learning Targets

The aim of the webinar is to make better accessible issues that arise in practice **around audits**, such as:

- Computerised systems – a new aspect in the compliance landscape?
- What are computerised systems from an auditor's perspective?
- Are computerised systems "formalised" auditable / inspectable?
- What do audits / inspections reveal and what do they sharpen your eyes on?
- How does understanding for the compliance of computerised systems arise?
- Compliance, a necessary evil or a tool for controlling costs?

Target Group

The webinar is aimed at managers from all areas of quality, automation, IT and technology, who, as auditors or auditees, have to deal with computerised systems / data integrity with regard to the preparation, implementation and / or follow-up of internal / external audits and official inspections.

Speaker



Dr Timo Kretzschmar

Senior Consultant, anapur AG Region Wien

Dr Timo Kretzschmar can look back on over 25 years of professional experience. From 2003 to 2016, he worked as a Q-Manager and auditor of a bioanalytical CRO in the GxP area and from 2016-2019 as an inspector for computerised systems at the Austrian pharmaceutical authority AGES Medical Market Authority / BASG. Since mid-2019 he is active as a senior consultant at anapur AG Region Vienna.

Registration for the GxP Webinar
"Audits / Inspections of Computerised Systems - Gaining Practical Insight"
on Wednesday, 22 July 2020, 14:00 – 16:00 h CEST

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Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Fees (plus VAT)

Single participation: € 199,- for ECA Members

Single participation: € 249,- 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 € 211,65

11-20 Persons € 186,75

more than 20 Persons € 161,85

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

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.

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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Please tick:

- Single Participation**
- Group Participation**
 - 3-10 Persons
 - 11-20 Persons
 - more than 20 Persons

Important:
Deadline is 12 noon on
21 July 2020

Title, First Name, Last Name

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General Terms and Conditions

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1. We are happy to welcome a substitute colleague at any time.

2. If you have to cancel entirely we must charge the following processing fees:

Cancellation until 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance.

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