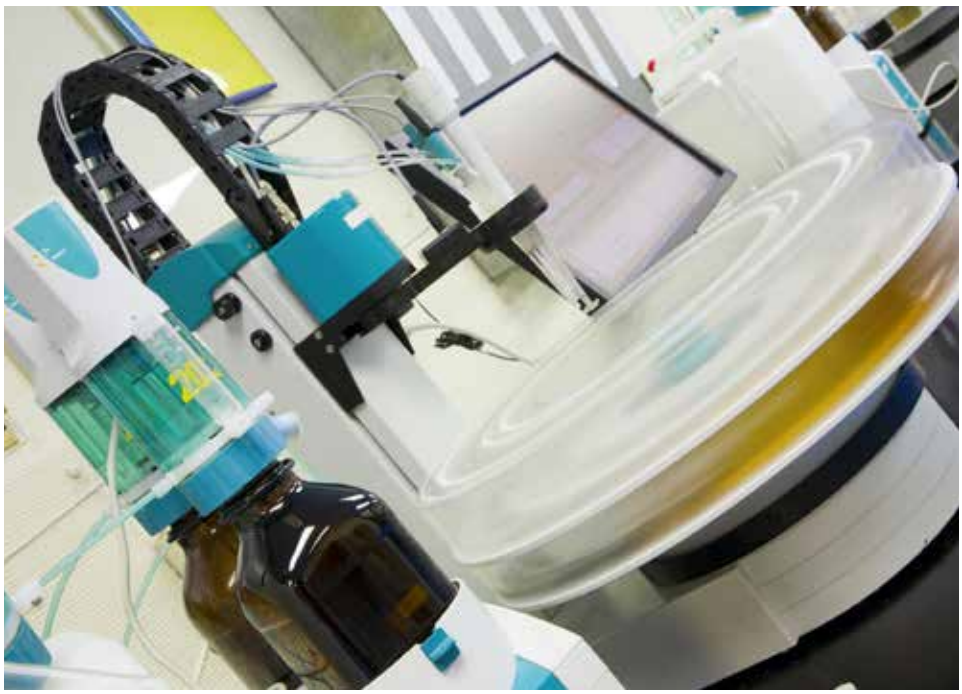
ECA ACADEMY

GMP Webinar

Requirements regarding Qualification of Laboratory Equipment in the EU - does the revised Annex 15 also apply?

Date:
Thursday, 14 April 2016, 14.00 – 15.30 h (CEST)

Speaker:
Dr Bernd Renger



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

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GMP Webinar: Requirements regarding Qualification of Laboratory Equipment in the EU

Background

The qualification of equipment is an essential requirement in the EU GMP Guide and in the revised Annex 15. Yet, compared to USP chapter <1058>, none of the two documents provide any details related to lab equipment. With the revision of Annex 15, the question arises whether Annex 15 also applies to laboratory equipment.

Educational Objectives

What are the requirements for the qualification of laboratory equipment in the EU?
Who is responsible for the qualification of laboratory equipment?

- What delegation possibilities are available?
- How to handle external service providers for the qualification of laboratory equipment?
  - Is a contract needed?
- Is the revised Annex 15 also valid for the qualification of laboratory equipment?
  - Are user requirement specifications/ functional specifications for laboratory equipment mandatory?
  - Are FAT/SAT required for laboratory equipment – and meaningful?
  - What does PQ mean regarding laboratory equipment?
  - Is the combination of qualification stages possible?
  - Conditional releases – are they also possible with laboratory equipment?
- Can USP chapter <1058> also be used as state of the art in Europe?

Target Audience

Addressed is laboratory personnel involved in qualification activities of laboratory equipment. Quality Assurance staff, who is interested in laboratory equipment qualification as well as - of course - manufacturers of laboratory equipment and service providers in the qualification of laboratory equipment are also addressed.

Speaker

Dr. Bernd Renger
Dr Renger is a Qualified Person and runs his own consultancy. Prior to that he was VP Quality Control at Vetter Pharma-Fertigung GmbH. He began his career at Hoechst AG in 1977 and has since held various management positions in the quality area at Mundipharma, Byk Gulden (today Takeda), as well as at Baxter BioScience AG in Vienna. Dr Renger was a member of the Board of the ECA Foundation and is a member the ECA Visual Inspection Group and the ECA Quality Control Group and Immediate Past Chair of the European QP Association.

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.

Fees (plus VAT)

Single participation: € 149.- for ECA Members
Single participation: € 199.- for non-ECA Members (This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/eca_about.html.)

Group Participation (fee per person):
3-10 Persons € 169,15
11-20 Persons € 149,25
more than 20 Persons € 129,35

Technical Requirements

To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers.
Your Internet browser must have following features to use the GMP Webinar system:
1. Adobe Flash-Player must be installed.
2. Javascript must be allowed.
3. Port 1935 must be released.
Please read the detailed technical requirements in this document:
http://www.gmp-compliance.org/webinar/webinar_requirements.htm

Registration

By mail, fax, 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.

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.

Do you have any questions?

For questions regarding content:
Mr Sven Pommeranz, phone +49-(0)6221-844447
E-Mail: pommeranz@concept-heidelberg.de

For questions regarding technical aspects:
Mr Matthias Zimmermann, phone phone +49-(0)6221-844459
zimmermann@concept-heidelberg.de.

Registration for the GMP Webinar: Requirements regarding Qualification of Laboratory Equipment in the EU
on 14 April 2016, 14.00 – 15.30 h (CEST)
Speaker: Dr Bernd Renger
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34
or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
☐ **Group Participation**
  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important:
Deadline is 12 noon on 13 April 2016

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