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GMP Webinar *Recording*
URS & Risk Analysis

Qualification for Suppliers and pharmaceutical users

Date of the recording: 11 September 2018

Speaker: Holger Fabritz, VeriQum

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

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Background

When a technical project is launched, it is often not yet clear which GMP requirements exist to what extend. Even though the process know-how lies with the pharmaceutical manufacturer, they usually expect a GMP-compliant system from the equipment manufacturer and reference regulations from the world of EU and FDA guidelines. In addition, compliance to many internal SOPs is also demanded. That makes it difficult, if not impossible, for equipment manufacturers to build and deliver products in compliance with all these vague requirements. At this point, user requirement specifications (URS) and risk analyses come into play. A risk analysis helps with determining which aspects are relevant for the quality and therefore subject to the mandatory qualification. These are summarised in the URS and submitted to the equipment manufacturer – or vice versa? This means to invite offers based on the URS and perform a risk analysis together with the equipment or system supplier later. After the change in EU regulations (EU GMP Annex 15), both documents will definitely be part of the qualification. The URS will then not be limited to procurement anymore; instead, it will be a living document within the system lifecycle – an approach which has been adopted from computer system validation. Besides the specification of the scope of delivery, the approach also describes further requirements to be met during the system lifecycle and thereby the test specifications for qualification and validation.

Educational Objectives

This webinar shows how requirements can be laid down between the pharmaceutical client and the technical supplier in technical projects. Assistance in preparing URS and risk analyses will enable the development of a structured and comprehensible qualification process.

- Main features and objectives of GMP risk analysis and User Requirement Specifications (URS)
- What should be considered in regards to document design and the combination of both these documents? What alternatives are there?
- For which processes/systems should the focus be on the URS and for which on the GMP risk analysis in order to define an appropriate extend of qualification?
- What does an efficient and save way to a rationale look like?

Target Audience

Target audience of this webinar are suppliers of equipment which has to comply with the requirements of the pharmaceutical user. But also pharmaceutical users (that are engineers and e.g. the head of production) who have to define these requirements.

Speaker

Holger Fabritz studied mechanical engineering and began his career at Merck in Darmstadt. He later joined NNE (Pharmaplan) and lead the department Quality & Validation Assurance. In this function he managed many Validation and GMP-Compliance projects within the pharmaceutical industry. Since 2016 he has his own consultancy business VeriQum and focuses on consulting in the Pharmaceutical and Biotech Industry.

Fees (plus VAT)

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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 *Recording* URS & Risk Analysis of 11 September 2018, Speaker: Holger Fabritz, VeriQum
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