ECA Academy
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GMP Webinar

Covid-19 and Data Integrity – Managing Compliance Risks in Analytical Instrument Qualification and Calibration

Date:
Wednesday, 01 July 2020, 14.00 -15.30 h CEST

Speaker:
Dr Bob McDowall, R.D.McDowall Ltd.
and
Dr Christopher Burgess, Burgess Analytical Consultancy Ltd.

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

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Background
The manufacture of pharmaceutical products is continuing during the Covid-19 pandemic. However, with limitations on travel and requirements for social distancing it may be difficult for a service engineer to come to a facility to perform repairs, preventative maintenance and periodic requalification of analytical instruments.

Educational Objectives
This webinar focuses on steps that a laboratory can take to maintain the calibration and qualification of analytical instruments to ensure the integrity of data during this pandemic and minimize compliance risk. The following topics will be covered:

- Current approaches by Regulatory Authorities to inspections during the pandemic
- Regulatory requirements for calibration and qualification of analytical instruments
- Overview of USP <1058> and the importance now of Performance Qualification (PQ) when a service engineer is to available for on-site service and qualification of instruments
- Justifying your approaches for deviating from your procedures based upon a risk assessment
- Importance of historical baseline data and trending
- Practical approaches discussed for the following instruments: HPLC chromatographs, Analytical balances and pH meters, UV-vis and IR spectrometers, Electronic pipettes

Target Audience
This webinar is designed for analytical chemists & scientists, quality control and quality assurance personnel involved with instrument qualification and calibration and R&D laboratory personnel operating under GMP.

Speakers

Dr Bob McDowall, R.D.McDowall Ltd., UK
Analytical chemist with over 45 years' experience including 15 years working in the pharmaceutical industry and afterwards working for the industry as a consultant. Bob is an trained auditor and he has been involved with the validation of computerised systems for over 30 years and is the author of books on the validation of chromatography data systems and practical approaches for data integrity and data governance in regulated laboratories. He is a core member of the GAMP Data Integrity SIG.

Dr Christopher Burgess, Burgess Analytical Consultancy, UK
He is an analytical chemist with more than 45 years' experience in the pharmaceutical industry in Quality Control and Quality Assurance initially and then within international consultancy. He is a "Qualified Person" in the European Union. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and re-elected 2015 to 2020. He is also a member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters <1224>, <1225> and <1226>. In addition, he is a member of the Executive Board of European Compliance Academy and Chairman of the Analytical Quality Control Group.

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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For questions regarding technical aspects please contact:
Ms Nicole Bach, phone +49(0)62 21 - 84 44 22
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Registration for the GMP-Webinar: "Covid-19 and Data Integrity – Managing Compliance Risks in AIQC"
on Wednesday, 01 July 2020, 14.00 -15.30 h CEST
Speakers: Dr Bob McDowall and Dr Christopher Burgess
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 for registration is 12 noon on 30 June 2020

Title, First Name, Last Name

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General Terms and Conditions
If you cannot attend the conference you have two options:
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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