ECA Academy
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GMP Webinar
To certify or not to certify: Batch Deviations and QP Certification

Date:
Thursday, 23 July 2020, 14.30 -16.00 h CEST

Speaker:
Sue Mann
Sue Mann Consultancy

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

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Background
Annex 16 (Certification by a Qualified Person and Batch Release) of the EU GMP Guide describes the "handling of unexpected deviations". A batch with an unexpected deviation concerning the manufacturing process may be certified if the result of a risk analysis performed shows that "the potential impact of the deviation on quality, safety or efficacy of the batch(es) concerned and conclusion that the impact is negligible."
This flexibility might sound reasonable but puts a lot of responsibility on the QPs. There will always be borderline cases and ambiguities.

Educational Objectives
- Batch deviations and QP Certification: degrees of freedom and limits as defined in the guidance
- Discuss based on real-life scenarios:
  - Potential risks and impact
  - Batch certification possible or not
  - Consequences and further actions

Target Audience
This Webinar has been designed for EU Qualified Persons (QP) but also QA personnel, upper management functions and other interested people who want to be informed about QP challenges when certifying batches.

Speaker

Sue Mann
Sue Mann Consultancy, U.K.
Sue Mann is a Qualified Person and a QP Assessor in the U.K. working on behalf of the MHRA, representing the Royal Pharmaceutical Society. Sue also works as a consultant and has more than 38 years experience in the Pharmaceutical Industry. In her last position, Sue was Vice President of International Quality Assurance at Shire Pharmaceuticals, before founding her own company.

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 € 211,15
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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.

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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 Webinar: "To certify or not to certify: Batch Deviations and QP Certification "
on Thursday, 23 July 2020, 14.30 -16.00 h CEST
Speaker: Sue Mann, Sue Mann Consultancy
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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Important: Deadline for registration is 12 noon on 22 July 2020

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