



# GMP Webinar *Recording*

## **To certify or not to certify: Batch Deviations and QP Certification**

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>).

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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

11-20 Persons € 186,75

more than 20 Persons € 161,85

## Registration

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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" of 23 July 2020

**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](http://www.gmp-compliance.org).

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