



GMP Webinar **Human Error**

Date:

Wednesday, 29 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

Human Error can not be completely avoided. We are finding that as processes become more and more improved and better controlled, often, Human Error becomes more visible. But it seems that the pharmaceutical industry still struggles to recognise and correctly addressing types of human error and regulators see human error only as a last resort. Chapter 1 of the EU-GMP Guidelines (1.4, xiv) state "where human error is suspected or identified as the cause, this should be justified, having taken care to ensure that process, procedural or system-based errors or problems have not been overlooked...". Problems appearing as human error should always be explored further. Human Error is rarely the root cause of a non-conformance. But sometimes it is – and sometimes it's a symptom of another underlying problem.

Educational Objectives

In this Webinar we will discuss

- What is behind "Human Error"?
- The link to human behaviours
- Human Error rates how many is too many?
- Tips for reducing human errors

Target Audience

This Webinar has been designed for upper management functions, QA personnel and other GMP functions such as GMP Compliance Managers.

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 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 plugin. 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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General Terms and Condition

If you cannot attend the conference you have two options:

. 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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Terms of payment: Payable without deductions within 10 days after receipt of invoice. Important: This is a binding registration and above fees are due in case of cancellation or non-appearance if you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!