



GMP Webinar Self Inspection

(How to manage and conduct internal GMP-Audits)

Date:

Tuesday, 21 September 2021, 14.00 -15.30 h CEST

Speaker:

Grant Mordue

Pro-Active GMP Consulting



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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

Background

In the **EU Guide to GMP, Chapter 9** on Self Inspection it is said that "self inspections should be conducted in order to monitor the implementation and compliance with Good Manufacturing Practice principles and to propose necessary corrective measures". Basically this is pretty much similar to an external audit at a third party manufacturer or a supplier. But there are some special aspects to consider.

One special challenge for internal auditors is to be team member on the one hand but to question established practices and to identify gaps on the other hand. In this case, the (internal) auditor is an extension of the quality system whose purpose is to limit the risk to patient, while being part of the quality system in question.

Educational Objectives

The aim of this webinar is to provide participants with a comprehensive yet compact on:

- Set up of the self inspection programme
- Preparation and planning the audit
- Who is auditing?
- Differences to an external audit; challenges, possible problems and solutions
- How to write a self inspection report

Target Audience

Personnel involved in planning, managing and conducting GMP self inspections.

Speaker



Grant Mordue

Director at Pro-Active GMP Consulting Ltd., UK

Before starting his consultancy business in 2020, Grant Mordue was Director Commercial Quality Assurance at Gilead Sciences. He also held QA positions at Sandoz International and GlaxoSmithKline.

Fees (plus VAT)

Single participation: € 249,- for ECA Members

Single participation: € 299,- for non-ECA Members

(This fee does not include the ECA Membership. You will find more about the ECA Membership at 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 EUR 254,15

11-20 Persons EUR 224,25

ab 21 Persons EUR 194,35

Registration

By mail, fax, e-mail or online on the Internet at 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

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,

Phone +49(0)6221 / 84 44-0, Telefax +49(0)6221 / 84 44 34

info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?

For questions regarding content please contact:

Mr Wolfgang Schmitt, phone +49 (0) 62 21 / 84 44 39

E-mail: w.schmitt@concept-heidelberg.de

For questions regarding organisational aspects please contact:

Mr Rouwen Schopka, phone +49 (0) 62 21 / 84 44 13

E-mail: schopka@concept-heidelberg.de

Registration for the GMP-Webinar: "Self Inspection" on Tuesday, 21 September 2021, 14.00 -15.30 h CEST

Speaker: Grant Mordue

Please fax to CONCEPT HEIDELBERG, +49 (0) 62 21 / 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 20 September 2021**

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

Street

Postal Code/City

Phone

Fax

E-Mail (mandatory for your registration)

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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a full refund of fees paid.

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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)!