



GDP Webinar

Responsibilities at GDP

Date:

Tuesday, 18 January 2022, 14:00 – 15:30 h CET

Speaker:

Dr Afshin Hosseiny, Chair of the European GDP Association



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

The globalisation of the pharmaceutical supply chain has created new challenges for the manufacture and supply of medicinal products in various markets. Directives, Guides, Guidelines and initiatives from various regulatory bodies lead the way in this development and define expectations and requirements, where Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) are closely linked.

In 2013 the revised new "Guidelines on Good Distribution Practice of Medicinal Products for Human Use" were published. Chapter 2 "Personnel" defines the qualification requirements, tasks and responsibilities of all staff and the Responsible Person (RP).

The requirements to be met include the following:

- The responsibility, role and interrelationships of all personnel should be clearly defined.
- Responsibilities and roles of employees working in key positions should be defined in written job descriptions, including arrangements for deputy duties.
- All employees involved in the distribution of medicinal products need to be trained in order to comply with the requirements defined in the GDP Guidelines.

Educational Objectives

This webinar aims to give participants a comprehensive yet compact overview on the various responsibilities at GDP. The following topics will be covered:

- What is GDP
- What activities are classed as GDP relevant
- Who is involved in GDP activities
- Who is responsible for these activities
- Is there any shared responsibility (GDP & GMP)
- What to do when things go wrong
 - Who should deal with problems
 - Who should be told

Target Audience

The webinar is aimed at coworkers and high-level personnel from the following industries:

- Pharmaceutical manufacturers (e.g. logistics and QA),
- Drug wholesaler,
- Logistics companies,
- External warehouses,
- Further service providers offering services for the distribution of pharmaceuticals.

Speaker



Dr Afshin Hosseiny, European GDP Association and Tabriz Consulting, U.K.

Afshin Hosseiny is Chair of the European GDP Association. He is also Chairman of the Executive Board of the ECA Foundation. Before working as a consultant, he was Director of Quality for the Global Supply Chain at GSK.

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 <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 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

<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

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

Tel. +49(0)6221/8444-0, 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:

Dr Markus Funk, phone +49(0)62 21 - 84 44 40,

Email: funk@concept-heidelberg.de.

For questions regarding technical aspects please contact:

Ms Nicole Bach, phone +49(0)62 21 - 84 44 22

Email: bach@concept-heidelberg.de

Registration for the GDP Webinar: Responsibilities at GDP on Tuesday, 18 January 2022, 14.00 – 15.30 h CET

Speaker: Dr Afshin Hosseiny, Chair of the European GDP Association

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 is 12 noon on
17 January 2022**

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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will

receive a full refund of fees paid.

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!)