



GDP Webinar

GDP for APIs

Date:

Thursday, 01 October 2020, 14.00 – 15.30 h CEST

Speaker:

Dr Nicola Spiggelkötter, Knowledge & Support



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

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Background

Since September 2015, the "Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use" have been obligatory. The driving force behind these Guidelines is the combat against falsified drug substances and drug products. It is intended to control the entire supply chain and thus to mitigate the risk associated with complex distribution pathways. Well trained staff has to ensure that all the requirements of the guidelines are met. In several sections of the Guidelines, it is pointed out that a thorough training of the employees is important.

Educational Objectives

This webinar aims to give participants a comprehensive yet compact overview of current expectations concerning GDP for APIs.

The topics addressed are:

- Regulatory requirements and guidance
 - "Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use"
 - "WHO Good trade and distribution practices for pharmaceutical starting materials"
 - Ensuring compliance with the current requirements
- EU GDP for finished medicinal products and EU GDP for APIs: Similarities and differences
- Critical evaluation of individual aspects with regard to GDP for APIs
- Outlook: Where is the trend heading?

Target Audience

This webinar is designed for all persons from companies involved in the distribution and supply of APIs. Those are e.g. coworkers and high-level personnel from the following industries:

- API manufacturers
- API distributors and traders
- Pharmaceutical manufacturers
- Logistics companies
- External warehouses
- further service providers offering services for the distribution of APIs

Speaker



Dr Nicola Spiggelkötter, Knowledge & Support

Dr Nicola Spiggelkötter is an independent management consultant with a focus on pharmaceutical logistics and strategy consulting. Numerous scientific publications, teaching positions both nationally and internationally, as well as being a member of advisory boards round off her profile.

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 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.

Do you have any questions?

For questions regarding content please contact:

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

E-Mail: funk@concept-heidelberg.de.

For questions regarding technical aspects please contact:

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

email: schopka@concept-heidelberg.de

Registration for the Webinar: GDP for APIs

on Thursday, 01 October 2020, 14.00 – 15.30 h CEST

Speaker: Dr Nicola Spiggelkötter, Knowledge & Support

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
30 September 2020

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!)