



# GDP Webinar

## The risk-based approach and GDP

Date:  
Monday, 28 September 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

The risk-based approach is a fundamental requirement for processes in the GDP environment. Quality risk management is one of the mandatory basic elements. It is applicable to a variety of activities and processes such as temperature mapping studies, supplier qualification, deviations and change control.

## Educational Objectives

This webinar aims to give participants a comprehensive yet compact overview of the concept and the implementation of a risk-based approach.

The topics addressed are:

- Regulatory requirements for quality risk management (QRM) in the GDP environment
- Application of QRM in the qualification of service providers
- Application of QRM in the qualification of facilities
- Application of QRM for deviations, CAPAs and change control

## Target Audience

This webinar addresses itself to all who want to get a compact and comprehensive overview of current expectations about quality risk management at GDP. Those are e.g. 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 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 EUR 211,65  
11-20 Persons EUR 186,75  
more than 20 Persons EUR 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?

For questions regarding content please contact:  
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Registration for the Webinar: The risk-based approach and GDP on Monday, 28 September 2020, 14.00 – 15.30 h CEST

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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).

Please tick:

- Single Participation**  
 **Group Participation**
- 3-10 Persons
  - 11-20 Persons
  - more than 20 Persons

**Important:**  
Deadline is 09.00 am  
on 28 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 %.

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