



GVP Webinar

Pharmacovigilance

Inspections/Audits & the Role of the QPPV

Date:

Wednesday, 19 August 2020, 14.00 - 15.30 h CEST

Speaker:

Dr Bianca Scholz, Germany, ScholzPharma GmbH,
Consulting, Audit & Projectmanagement

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

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Background

In recent years, the pharmacovigilance system (PVS) has turned into a highly complex procedure. Numerous regulations require marketing authorization holders to significantly increase PV standards and to review them regularly. For example, the EMA has recently published a new document on *follow-up activities following pharmacovigilance inspections*.

What are the tasks and responsibilities of the Qualified Person for Pharmacovigilance (QPPV)? How to implement the requirements in practice - correct and inspection-ready? What is the best way to fulfil the requirement to conduct audits and pharmacovigilance inspections?

This webinar will answer these and other questions and show risk-based approaches on how to deal with the increasing number of audits - e.g. by focusing on audits particularly in critical areas. In this way, time and resources can be saved.

Programme

- Role of the QPPV
- Responsibilities of the QPPV
- Review of the PV system / regular audits
- Audits in an international environment:
 - Planning
 - Preparation
 - Execution
 - Follow-up of pharmacovigilance inspections: Post-inspection actions and CAPA management
- Remote audits, joint audits

Target Group

This seminar is for QPPVs and all employees, specialists and managers of companies and institutions who are responsible for the pharmacovigilance system and/or for the planning and conducting of PV audits / inspections.

Speaker



Dr Bianca Scholz, ScholzPharma GmbH, Consulting, Audit & Projectmanagement

Dr Scholz has been Managing Director of Scholz Consulting since 2008. She advises clients in the field of GVP, GCP, GLP and GMP with a focus on Quality Management, Audits and

Inspection and is auditor DGQ/EQO and specialized pharmacist for drug information / community pharmacy. Dr Scholz conducts numerous audits in the pharmacovigilance area (globally).

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 www.gmp-compliance.com. 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

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Do you have any questions?

For questions regarding content please contact:

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For questions regarding organisational aspects please contact:

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Registration for the GVP Webinar

"Pharmacovigilance Inspections/Audits & the Role of the QPPV"
on Wednesday 19 August 2020, 14.00 - 15.30 h CEST

Speaker: Dr Bianca Scholz

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
18 August 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).

German law shall apply. Court of jurisdiction is Heidelberg.