ECA Academy
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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?
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Registration for the GVP Webinar
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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

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