Pharmacovigilance Oversight

How to guarantee quality and to manage pharmacovigilance audits and inspections succesfully in PV oversight activities

29 September 2020 - Amsterdam

110 € Early Bird discount
for enrolment by 01/09/2020

Course Language: English

Amsterdam

The Netherlands

Tuesday 29 September 2020

08:30-17:00

*Taking part in our training courses, you support **"The Vase of Flowers"** project*

For additional information: +39 (0)35.515684 | training@LSacademy.com www.LSacademy.com

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Introduction

The implementation of an effective pharmacovigilance function is high on the list of priorities for pharmaceutical companies. Pharmacovigilance management is a regulatory obligation for all companies holding an Authorization into Commerce (AIC) or an Authorization for Production (AP). Updates and legislative obligations on pharmacovigilance have significantly increased, making the management of related processes complex and expensive for the pharmaceutical company. Therefore, resorting to outsourcing certain processes or pharmacovigilance services may be a solution. Managing third parties naturally requires oversight by the AIC holder, as well as implementation and management of adequate supporting documentation, so that the process can be under control and be reliable. In particular, the management of third parties can envisage a diversified approach according to the authorization procedure of the pharmaceutical product, and thus foreseeing different types and levels of responsibilities for the third parties involved. The course will address:

- The key aspects related to audits of service providers by the marketing-authorisation holders (MAHs) or regulatory authority inspections
- What makes a successfully run audit or inspection regardless of the findings
- Practical information and advice on service provider activities
- The keys to preparing for and effectively managing audits and/or inspections, as well as gaining insight into the roles and expectations of key functions.

To whom it may concern

This course is intended for all those who are involved in third-party management in pharmacovigilance (responsible for pharmacovigilance, Quality Assurance, Regulatory, Legal, Procurement) in BioPharmaceutical companies, Medical device companies, PV Service Providers and PV Consultants/Contractors.

Type of Training

Lectures, discussions, and practical exercises

Course Language

The course will be in English.

Update 12.03.2020

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Programme

Course Language: English

The training course will cover the following aspects:

- Brief analysis of the legislation in force
- Oversight vendor concept, including the use of key performance indicators (KPIs)
- Practical information and advice on service provider activities
- Implementation of a correct oversight of the third parties SDEA
- Analysis of the contractual structure
- Key aspects related to audits
- Key aspects related to inspections by Regulatory Authorities

Agenda

8:30 - 9:00		Participants registration
9:00		Course commences
10:45 - 11:00		Coffee Break
12:30		Lunch
15:15 - 15:30		Coffee Break
16:30 - 17:00		Q&A and Conclusion

Participant experience

To attend this course, it is advisable that participants have a basic knowledge of the Good Pharmacovigilance Practices (GVPs) and at least 1 year of pharmacovigilance experience.

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Lecturer

Ms. Parminder Kaur - *CEO & EU QPPV RegPak BioPharma Consulting - Amsterdam, The Netherlands*

Parminder Kaur is the owner of RegPak BioPharma Consulting based in Amsterdam (The Netherlands) and Bucharest (Romania). RegPak provides consulting services in regulatory affairs and pharmacovigilance. In 2019, Parminder launched a medical devices CRO. She has played a major role in setting the in-house RA and PV systems in compliance with the European regulations at various companies; and has assisted various companies during Inspections and Audits conducted by EU Regulatory Authorities. Parminder has received many international awards for her expertise and continuous efforts in promoting knowledge via educational programmes. Parminder had been a speaker, panellist and masterclass trainer at various international conferences.

At the end of the training you will able to

- Understand the importance of key performance indicators (KPIs) within the PV organisation
- Learn the pharmacovigilance inspections and key PV activities
- Ensure compliance with assessments of risk and CAPA and preventative actions
- Understand the processes/activities/documentation that needs to be reviewed and how to set up its logistics accordingly
- Learn practical tips to be used on a daily basis

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TO REGISTER FOR THE COURSE YOU CAN FILL IN AND SEND

THE REGISTRATION FORM OR DIRECTLY **REGISTER ONLINE**

REGISTRATION FEES:

- ☐ Early bird: **€ 880,00*** until 01/09/2020
- ☐ Ordinary: **€ 990,00***
- ☐ Freelance – Academy – Public Administration**: **€ 490,00***

***For Italian companies: + 22% VAT**

The fee includes: tuition, teaching materials, lunches and coffee breaks, organizational office assistance, attendance certificate.

****Early Bird discount not applicable to Freelance – Academy – Public Administration fee**

Methods of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer or by credit card. If paying by bank transfer please attach proof of payment to the registration form. Bank transfer payable to:

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BG)

P. IVA **03633040161**

Banco BPM - Filiale di Carobbio Degli Angeli

IBAN: **IT81 F 05034 53960 000000003450**

SWIFT CODE: **BAPPIT21AY5**

For further information:

Organisational Office & Scientific Manager

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Please fill in and send: **(+39) 035.4501262** | **training@LSacademy.com**

Surname _____ **Name** _____

Company _____ **Job title** _____

Address _____

City _____ **Post code** _____

Tel. _____ **Fax.** _____

E-mail _____

Special Dietary Requests _____

Invoicing details

Company name _____

Address _____

Mail address (If different) _____ **Post code** _____

City _____

VAT number _____ **Invoice recipient code** _____

Terms & conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants.

Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the course date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities. LS Academy reserves the right not to accept registrations not compatible with the event's target audience.

The course will proceed with a minimum of 8 participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

In accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, we inform you that EasyB S.r.l. (with headquarter in Via Roma 20, Alzano Lombardo, Bergamo, Italy, VAT number IT03633040161) will use your personal data voluntarily provided by you only with the consent and in compliance with the principles dictated by the European Regulations on the protection of personal data for sending newsletters, for marketing purposes (sending advertising material, market research and commercial communication) and for communication purposes to third parties (lecturers), also for marketing goals. You can read the complete information, including your rights and the procedures for the exercise of the same, following this link.

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LSACADEMY.com **Date** _____ **Signature** _____