HIGHLIGHTED COURSE

Audits and Inspection in Pharmacovigilance

April, 4 - 5 | 2023
ONLINE

Learning objectives

After the completion of the course, participants should be able to:

- Understand the specific requirement of a PV Quality System and implement or improve this process in their own organisation
- Learn the key phases of the PV audit both as an auditor and as an auditee.
- Focus on most important interactions of a PV System and PV processes usually reviewed during GVP audit and inspections
- Learn how to approach and face up a GVP audit
- Learn how to prepare organization for a GVP inspection understanding the regulatory expectations

Purpose

Well-designed and well-conducted pharmacovigilance audits allow pharmaceutical companies to identify any existing gaps or risks in their PV systems and procedures and to define activities and priorities for the continuous improvement of their PV quality systems, with the aim to ensure compliance of the PV system to national and international legislation and recognised standards and to be ready to face GVP regulatory inspections. A deep review of the most important PV processes and interactions between internal and external stakeholders will outline more common areas of improvements according to auditors/inspectors expectations.

Speaker

Patrizia Rotunno

The speaker is a pharmacovigilance expert dealing with Pharmacovigilance Systems since more than 20 years. With a Regulatory Affairs background she was QPPV of a medium sized company having the opportunity to manage almost all pharmacovigilance processes within pharmacovigilance system and its quality system.
Five years ago, she started working as Pharmacovigilance Consultant to assist clients improving compliance with the pharmacovigilance legislation and Good Vigilance Practices, from start-up phase of a pharmacovigilance system to creation and/or review and management of specific pharmacovigilance documents. In the last five years she has also conducted several GVP audits to client's pharmacovigilance systems or to service providers/business partners on behalf of the clients and she has supported some pharmaceutical companies in preparing and facing up to GVP inspections.

Who should attend?

For professionals working in the following
areas:

- Pharmacovigilance
- Drug Safety and Risk Management
- Regulatory Affairs
- Clinical Research
- Quality and Compliance

Program

DAY 1
9.00 **Introduction to the course**

9.10 **What are the main regulatory requirements and the organization of the PV System?**
- Main requirements and key points
- Key PV processes
- Interactions with other company departments
- **Q&A Time**

10.50 **coffee break**

11.10 **GVP audit**
- Regulatory requirements
- Risk based approach
- Audit announcement, preparation and conduction
- CAPA plan monitoring
- KPIs on audit activities
- **Q&A Time**

13.00 **Closure of day one**

DAY 2
9.15 **Focus on GVP Inspections requirements**
- Regulatory requirements
- Risk based approach
- Inspection announcement
- **Q&A Time**

10.30 **coffee break**

10.50 **GVP inspection readiness**
- key points in the preparation of inspection
- Interaction with other company departments
- GVP inspection days

11.30 **What are the main inspector's expectations?**
Sharing of most common finding and experience
Discussion

12.15 **KEY TAKEAWAYS**

12.30 **Closure of course**

TERMS OF PAYMENT

Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Firenze, IBAN IT81P0503402801000000007431, Bic/SWIFT BAPPIT21N25 made payable to Pharma Education Center S.r.l., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling. Attendance to the event will be allowed upon payment received. Invoice of payment will be issued after the second half of the month after the course.

For further information and/or further assistance please contact (+39) 055 7224179 or email: amministrazione@pharmaeducationcenter.it

COURSE/EVENT CANCELLATION

If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refound the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

CANCELLATION TERMS

In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

PARTICIPANT REPLACEMENT

It is possible to replace a participant attendance without additional cost, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement request within 5 days before the starting date of the course/event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

HOW TO REGISTER

Please, fill the form on the web site https://www.pharmaeducationcenter.it/

ENTRY FEE
900 €

750 € until March 4, 2023

Discounts are not cumulative

VAT not included

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