Postgraduate Certificate in Pharmacovigilance

Pharmacovigilance Auditing and Inspections

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem (ICH E2D). Pharmacovigilance auditing and inspections are crucial activities that ensure the quality and compliance of PV systems. In this explanation, we will discuss key terms and vocabulary related to PV auditing and inspections in the context of the Postgraduate Certificate in Pharmacovigilance.

1. Audit:
An audit is a systematic and independent examination of PV systems, processes, and procedures to assess their compliance with regulations, guidelines, and procedures. It aims to identify gaps, weaknesses, and areas for improvement and provide recommendations to ensure compliance and enhance the effectiveness of PV systems.
2. Inspection:
An inspection is a regulatory activity conducted by a competent authority to assess the compliance of PV systems with legal requirements, guidelines, and procedures. It involves an on-site visit to the pharmaceutical company and a review of its PV systems, documents, and records.
3. Good Pharmacovigilance Practices (GVP):
GVP are the detailed guidelines that provide a framework for the performance of PV activities by the marketing authorization holders (MAHs) and national competent authorities (NCAs). GVP modules cover various aspects of PV, such as risk management, signal management, and pharmacoepidemiological studies.

4. Quality Management System (QMS):
A QMS is a collection of processes, procedures, and policies that ensure the quality and compliance of PV systems. It includes various elements, such as quality manual, standard operating procedures (SOPs), training and development, internal audits, and management review.

5. Risk Management Plan (RMP):
An RMP is a document that outlines the measures to be taken to manage the risks associated with a medicinal product. It includes the identification of risks, assessment of their significance, and a description of the measures to be taken to mitigate them.

6. Signal Management:
Signal management is the process of identifying, evaluating, and prioritizing signals related to a medicinal product. It involves the use of various tools and techniques, such as literature searches, data mining, and statistical analysis.

7. Pharmacoepidemiological Study:

A pharmacoepidemiological study is a study that investigates the use and effects of a medicinal product in a large population. It provides information on the safety and efficacy of the product and helps to identify any rare or long-term adverse effects.

8. Audit Trail:
An audit trail is a record of all the activities related to a PV system. It includes information on the creation, modification, and deletion of documents, records, and data. An audit trail helps to ensure the traceability, accountability, and reliability of PV systems.

9. Non-Compliance:
Non-compliance is the failure to comply with regulations, guidelines, and procedures related to PV systems. It can result in warnings, fines, suspensions, or revocations of marketing authorizations.

10. Root Cause Analysis:
Root cause analysis is a problem-solving technique that aims to identify the underlying causes of a non-compliance or a deviation. It involves a systematic investigation of the event, its context, and its consequences.

11. Corrective and Preventive Action (CAPA):
CAPA is a process that aims to correct the non-compliance or the deviation and prevent its recurrence. It includes the identification, evaluation, and implementation of appropriate actions to address the root cause.

12. Change Management:
Change management is the process of planning, implementing, and monitoring changes to PV systems. It ensures that the changes are documented, validated, and communicated to the relevant stakeholders.

13. Training and Development:
Training and development are the activities that aim to enhance the knowledge, skills, and competencies of the PV staff. They include various forms of learning, such as on-the-job training, e-learning, workshops, and conferences.

14. Internal Audit:
An internal audit is an audit conducted by the pharmaceutical company itself to assess the compliance and the effectiveness of its PV systems. It provides feedback and recommendations to the management for improvement.

15. External Audit:
An external audit is an audit conducted by an independent third party, such as a regulatory authority or a contract auditor, to assess the compliance and the effectiveness of the pharmaceutical company's PV systems.

16. Remote Audit:

A remote audit is an audit conducted remotely, using digital tools and technologies, such as video conferencing, screen sharing, and file sharing. It enables the auditor to access the pharmaceutical company's PV systems and documents without physically visiting the site.

17. Competent Authority:
A competent authority is a regulatory body responsible for the oversight and the enforcement of PV regulations and guidelines. It includes national authorities, such as the FDA in the US and the EMA in Europe, and international organizations, such as the WHO and the ICH.

18. Marketing Authorization Holder (MAH):
A MAH is a legal entity responsible for the marketing and the distribution of a medicinal product. It is subject to the PV regulations and guidelines and is required to maintain PV systems to ensure the safety and the efficacy of the product.

19. Serious Adverse Event (SAE):
An SAE is an adverse event that results in death, hospitalization, disability, or other significant medical harm. It requires immediate reporting to the competent authority and the MAH.

20. Individual Case Safety Report (ICSR):
An ICSR is a report that contains information on an SAE related to a medicinal product. It includes the details of the patient, the product, the event, and the investigation.

In conclusion, pharmacovigilance auditing and inspections are complex and critical activities that require a deep understanding of key terms and vocabulary. This explanation has provided an overview of the key concepts related to PV auditing and inspections, including audit, inspection, GVP, QMS, RMP, signal management, pharmacoepidemiological study, audit trail, non-compliance, root cause analysis, CAPA, change management, training and development, internal audit, external audit, remote audit, competent authority, MAH, SAE, and ICSR. These concepts are essential for the success of PV auditing and inspections, and their understanding is crucial for the practitioners in the field of pharmacovigilance.