



Pharmacovigilance Training Course: ICSR Processing, Signal Management and Inspections



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Introduction:

Pharmacovigilance training course on ICSR processing, signal management and inspections is a 5-day course for drug safety, pharmacovigilance quality, regulatory and medical teams at marketing authorisation holders and health authority safety units, ending with a PV System Gap Assessment and Signal Management Procedure for a case company. Safety systems fail inspections when case reports miss timelines, coding is inconsistent, signals sit unassessed and the master file no longer matches practice. Nominees already process cases, review safety data or oversee PV activities, and work through case studies built on case, signal and audit records. CoreConcept Training Center delivers this pharmacovigilance course.

Course Objectives:

- Describe the pharmacovigilance system of a marketing authorisation holder, its legal basis in general terms and the duties it places on the company and its partners
- Maintain a pharmacovigilance system master file and define QPPV oversight, deputy cover and partner safety data exchange agreements
- Process individual case safety reports from intake and validity check through triage, MedDRA coding, causality assessment and expedited submission
- Run literature screening and signal detection, then validate, prioritise, assess and track signals to a documented decision
- Contribute to periodic benefit-risk evaluation reports and risk management plans, including additional risk minimisation measures and their effectiveness indicators
- Plan pharmacovigilance audits, prepare for inspections and turn findings into a PV system gap assessment and corrective action plan

Target Audience:

- Drug safety teams responsible for receiving, assessing, coding and submitting adverse event case reports
 - Safety science and medical review teams that evaluate aggregate data, signals and benefit-risk conclusions
 - Pharmacovigilance quality and compliance teams that maintain procedures, the master file, audits and inspection readiness
 - Regulatory affairs teams that coordinate safety submissions, periodic reports and risk management plans with authorities
 - Licensing and alliance management teams that negotiate and monitor safety data exchange agreements with partners
 - Health authority pharmacovigilance units that receive case reports, assess signals and review company safety systems
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Course Outline:

Day 1: Pharmacovigilance Foundations, Legal Basis and PV System Baseline

- Pharmacovigilance Definition, Scope and Post-Authorisation Safety Objectives
- Generic Legal Basis and Marketing Authorisation Holder Safety Duties
- International Harmonisation Guidelines Shaping Clinical Safety Data Management
- Pharmacovigilance System Components, Processes and Quality System Interfaces
- Current-State PV System Baseline Using a Process Inventory

Day 2: PV System Master File, QPPV Role and Partner Agreements

- Pharmacovigilance System Master File Structure, Annexes and Logbook
- QPPV Responsibilities, Deputy Arrangements and Oversight Reporting Lines
- Safety Data Exchange Agreements With Licensing and Distribution Partners
- PV Quality Management System Procedures, Training Records and Metrics
- Vendor and Affiliate Oversight Matrix for Outsourced Safety Activities

Day 3: ICSR Processing, MedDRA Coding and Literature Screening

- ICSR Intake Channels and Four Minimum Validity Criteria
- Seriousness, Expectedness and Triage Rules for Expedited Reporting
- MedDRA Coding Conventions for Reported Terms and Indications
- Causality Assessment Using Temporality, Dechallenge and Confounder Review
- Literature Screening Protocol, Search Strings and Duplicate Case Detection

Day 4: Signal Management, Periodic Benefit-Risk Reports and Risk Minimisation

- Signal Detection With Disproportionality Statistics and Case Series Review
- Signal Validation, Prioritisation, Assessment and Tracking Log Workflow
- Periodic Benefit-Risk Evaluation Report Sections and Integrated Conclusions
- Risk Management Plan Safety Specification and Pharmacovigilance Plan
- Additional Risk Minimisation Measures and Effectiveness Evaluation Indicators

Day 5: Case Study: PV System Gap Assessment and Signal Management Procedure

- Risk-Based PV Audit Programme and Audit Scope Planning
 - Inspection Readiness Storyboard, Document Requests and Interview Rehearsal
 - Case Company Master File and ICSR Workflow Gap Review
 - Case Signal Dossier Review From Detection to Safety Decision
 - Signal Management Procedure and Gap Assessment Completion and Defence
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Skills You Will Gain:

- Adverse Event Case Processing
- MedDRA Terminology Coding
- Causality Assessment
- Safety Signal Evaluation
- Aggregate Safety Reporting
- Risk Minimisation Planning
- Safety Data Exchange Agreement Control
- Pharmacovigilance Inspection Preparation

Why Attend This Course:

- Deliver a PV System Gap Assessment and Signal Management Procedure for a case company to the QPPV and the head of drug safety for approval
- Decide whether a case is valid, serious and due for expedited submission, and whether a signal is validated, refuted or escalated
- Avoid late case submissions, unassessed signals and outdated master file content that lead to critical audit and inspection findings
- Share triage checklists, coding conventions, signal tracking logs and inspection storyboards with drug safety and quality colleagues

Conclusion:

Back at work, the participant hands the QPPV and the head of drug safety a PV System Gap Assessment and Signal Management Procedure that ranks system gaps by inspection risk, assigns corrective actions and sets out how signals are detected, validated, assessed and closed. Management uses it to approve resourcing, revise safety data exchange agreements and update the master file, while safety scientists apply the procedure in routine signal review. After the first full signal review cycle, the unit should check timeliness, decision records and the closure of audit findings.

Frequently Asked Questions FAQ:

What should participants know before a pharmacovigilance course on ICSR processing and signal management?

Participants should already handle adverse event cases, safety data review, safety submissions or PV quality tasks, and understand basic medical terminology. Bringing an anonymised extract of a local case procedure, signal log or audit finding list lets them apply the case work to their own system.

How does a pharmacovigilance systems course differ from a hospital medication safety or medical device vigilance course?

It covers the safety system for authorised medicines run by companies and authorities: case reports, coding, signals, periodic reports, risk management plans, the master file and inspections. Hospital medication safety addresses prescribing and administration errors, and device vigilance covers complaints and field actions for devices.

Why does pharmacovigilance signal management need a documented procedure?

A documented procedure makes signal decisions traceable and consistent. It sets who screens data and how often, which statistical and clinical criteria trigger validation, how signals are prioritised and when outcomes reach risk management plans and product information, which auditors and inspectors check first.

What do participants take back from the pharmacovigilance training course on ICSR processing and inspections?

Participants take back a PV System Gap Assessment and Signal Management Procedure for a case company, with an ICSR triage checklist, a MedDRA coding conventions sheet, a signal tracking log, an agreement checklist and an inspection readiness storyboard to adapt.
