TOP 60

Pharmacovigilance Interview Questions and Expert Answers

A practical PV interview prep guide for Drug Safety Associate, PV Associate, Medical Reviewer, Safety Scientist, and entry-level pharma roles.

ICSR | MedDRA | GVP | Signal Detection | RMP

INTERVIEW READINESS MAP

- Core definitions
- Case intake & triage
- Coding & narratives
- Regulatory reporting
- Signals & risk
- Scenario answers

Downloadable blog asset

PHARMUNI

How to Use This Guide

Practice answer structure before memorising facts. Interviewers test judgment, documentation, and timeline awareness.

1 Learn the short answer

Give a clean definition first. Then add one practical PV example.

2 Add process evidence

Mention intake, duplicate check, MedDRA, QC, submission, and audit trail.

3 Use scenario language

Explain how you would prioritise risk, clarify missing data, and escalate on time.

4 Connect to the role

Match your answer to Drug Safety Associate, PV Associate, Medical Reviewer, or Safety Scientist duties.

Tip: do not present PV as only “data entry.” Show patient safety thinking plus compliance control.

PV Foundations

Definitions, purpose, and safety language used in almost every interview.

01 What is pharmacovigilance?

PV is the science and activities used to detect, assess, understand, and prevent adverse effects or other medicine-related problems. In interviews, connect it to patient safety and benefit–risk control.

02 Why is pharmacovigilance important?

It protects patients after medicines enter real-world use. Clinical trials are limited, so PV helps detect rare, delayed, or population-specific risks after launch.

03 What is an adverse event?

An AE is any unfavorable medical occurrence temporally associated with a medicinal product, whether or not it is related to that product.

04 What is an adverse drug reaction?

An ADR is a harmful and unintended response where a causal relationship with the drug is at least reasonably possible.

PV Foundations

Definitions, purpose, and safety language used in almost every interview.

05 What is the difference between AE and ADR?

AE is causality-neutral. ADR implies suspected causal relationship. Interviewers expect you to separate observation from assessment.

06 What is a serious adverse event?

A serious AE/ADR results in death, is life-threatening, requires or prolongs hospitalization, causes disability/incapacity, congenital anomaly, or another medically important condition.

07 What is severity?

Severity describes intensity, such as mild, moderate, or severe. It is not the same as seriousness, which is based on regulatory outcome criteria.

08 What is expectedness?

Expectedness compares the event with approved labeling or the investigator brochure. If nature or severity is not consistent, it may be unexpected.

PV Foundations

Definitions, purpose, and safety language used in almost every interview.

09 What are the four minimum criteria for a valid ICSR?

Identifiable patient, identifiable reporter, suspect product, and adverse event/reaction. If one is missing, request follow-up before regulatory submission.

10 What is an ICSR?

An Individual Case Safety Report is a structured report for a single patient safety case, including patient data, event, product, reporter, assessment, and narrative.

11 What is a SUSAR?

A SUSAR is a suspected unexpected serious adverse reaction. It is critical in clinical trials because it may trigger expedited reporting and safety actions.

12 What is a safety signal?

A signal is information suggesting a new or changed causal association between a medicine and event. It requires validation, assessment, and possible action.

ICSR Workflow

Case intake, triage, follow-up, narratives, and documentation control.

13 Walk me through ICSR case processing.

Intake → triage → duplicate check → validity check → coding → seriousness/expectedness/causality → narrative → QC → submission → closure with audit trail.

14 What do you check during triage?

Check seriousness, source, due date, product, patient, reporter, event terms, country, and whether the case is initial or follow-up.

15 How do you handle missing information?

Record what is available, identify critical gaps, send follow-up questions, track attempts, and document all actions according to the SOP.

16 How do you manage duplicates?

Compare patient identifiers, product, event, reporter, dates, and source. If duplicate, merge carefully and preserve case history and audit trail.

ICSR Workflow

Case intake, triage, follow-up, narratives, and documentation control.

17 What is follow-up in PV?

Follow-up is the process of obtaining missing or clarifying information. Seriousness, outcome, product details, onset date, and causality often need follow-up.

18 How do you prioritize PV cases?

Prioritize by seriousness, reportability, due date, data completeness, regulatory impact, and patient risk. Escalate early if timelines may be missed.

19 What is case narrative writing?

A concise medical story of the case. It should include chronology, suspect product, event, relevant history, action taken, outcome, and assessment.

20 What makes a strong case narrative?

Clear timeline, no speculation, correct medical terminology, important lab values, rechallenge/dechallenge, reporter view, and consistency with coded fields.

Coding & Medical Review

MedDRA, causality, dechallenge/rechallenge, and narrative precision.

21 What is MedDRA?

MedDRA is a standardized medical terminology used to code, retrieve, analyze, and present safety information across regulatory processes.

22 What are LLT and PT in MedDRA?

LLT is the lowest-level reporter term. PT is the preferred term used for analysis. Coding should preserve the reporter's meaning.

23 How do you choose the right MedDRA term?

Use the most specific term supported by source text. Do not code diagnoses or outcomes unless the source supports them.

24 What is an SMQ?

A Standardised MedDRA Query groups related terms to support signal detection and safety analysis for defined medical conditions or risks.

Coding & Medical Review

MedDRA, causality, dechallenge/rechallenge, and narrative precision.

25 How do you avoid over-coding?

Code only medically meaningful events, diagnoses, signs, symptoms, tests, and procedures supported by the source. Avoid duplicating the same concept.

26 What is product coding?

Product coding standardizes suspect, concomitant, and interacting medicines. It supports duplicate detection, regulatory reporting, and aggregate analysis.

27 What is dechallenge?

Dechallenge means the suspect product was stopped, reduced, or interrupted. Improvement after dechallenge can support causal assessment.

28 What is rechallenge?

Rechallenge means the product was restarted. Recurrence of the event after rechallenge may strongly support causality, if documented.

Coding & Medical Review

MedDRA, causality, dechallenge/rechallenge, and narrative precision.

29 What is causality assessment?

Causality assesses the relationship between suspect product and event using timing, dechallenge, rechallenge, alternative causes, and known safety profile.

30 How do you answer a causality question in interview?

Say you follow company SOP and applicable method. Then explain timing, medical plausibility, confounders, dechallenge/rechallenge, and documented evidence.

31 What is expedited reporting?

Expedited reporting is faster regulatory submission for qualifying serious and unexpected or otherwise reportable safety cases. Exact rules depend on region, product, and study phase.

32 What is E2B(R3)?

E2B(R3) is the ICH standard for electronic transmission of ICSRs. It improves structured safety data exchange between companies and regulators.

Regulatory Reporting

GVP, PSMF, aggregate reports, forms, and electronic submissions.

33 What is GVP?

Good Pharmacovigilance Practices are EU measures and guidance for performing PV activities, including systems, risk management, reports, signals, and safety communication.

34 What is a PSMF?

A Pharmacovigilance System Master File describes the marketing authorization holder's PV system, responsibilities, processes, databases, and compliance controls.

35 What is a PSUR/PBRER?

A periodic safety report summarizes worldwide safety data, benefit–risk evaluation, signals, exposure, and actions for an authorized medicinal product.

36 What is a DSUR?

A Development Safety Update Report is an annual safety report for investigational drugs, summarizing clinical trial safety data and benefit–risk information.

Regulatory Reporting

GVP, PSMF, aggregate reports, forms, and electronic submissions.

37 What is an RMP?

A Risk Management Plan describes important risks, missing information, pharmacovigilance activities, and risk minimization measures across the product lifecycle.

38 What is a CIOMS form?

A CIOMS form is a structured format historically used for international reporting of suspected adverse reactions, especially serious cases.

39 What is MedWatch Form FDA 3500A?

FDA Form 3500A is used for mandatory adverse event reporting when electronic submission is not required. Always follow current FDA and company requirements.

40 What is EudraVigilance?

EudraVigilance is the European system for managing and analyzing suspected adverse reactions for medicines authorized or studied in the European Economic Area.

Signals, Risk & Quality

Signal detection, benefit–risk, RMPs, QA, audits, and inspections.

41 How does signal detection work?

Teams collect safety data, run qualitative and quantitative reviews, validate potential signals, assess clinical relevance, and recommend action when needed.

42 What sources feed signal detection?

Spontaneous reports, literature, clinical studies, regulatory databases, aggregate reports, product complaints, social media where applicable, and medical information requests.

43 What is disproportionality analysis?

A statistical method that checks whether a drug-event pair is reported more often than expected in a database. It suggests patterns; it does not prove causality.

44 What is benefit–risk assessment?

Benefit–risk assessment weighs therapeutic benefits against known and potential risks. It supports labeling, risk minimization, and regulatory decisions.

Signals, Risk & Quality

Signal detection, benefit–risk, RMPs, QA, audits, and inspections.

45 What is risk minimization?

Actions that reduce risk, such as labeling, education, controlled access, pregnancy prevention programs, alerts, or additional monitoring.

46 What is additional monitoring in the EU?

It flags medicines under closer safety monitoring. Interview answer: explain that it improves awareness and reporting for specific products.

47 How do PV and QA interact?

QA ensures SOPs, training, audits, CAPA, vendor oversight, and inspection readiness. PV performs operational safety activities within that quality system.

48 What is vendor oversight in PV?

The company must ensure outsourced PV tasks meet agreements, SOPs, quality metrics, timelines, and audit expectations.

Signals, Risk & Quality

Signal detection, benefit–risk, RMPs, QA, audits, and inspections.

49 How do you prepare for a PV inspection?

Know SOPs, training records, case metrics, late submissions, CAPA, PSMF, agreements, audits, and evidence for decisions.

50 What is CAPA in PV?

Corrective and Preventive Action fixes root causes behind quality issues, such as late case submission, coding errors, or missed follow-up.

51 How do you ensure data integrity in PV?

Use ALCOA+ principles, validated systems, audit trails, access control, source traceability, version control, and timely documentation.

52 What PV databases might you mention?

Argus Safety, ArisGlobal LifeSphere, Veeva Vault Safety, EudraVigilance, FAERS, VigiBase, and local authority systems depending on the role.

Scenario & HR Answers

Role-fit, deadlines, pressure, and fresher interview preparation.

53 How do you handle a literature case?

Screen the article, identify valid case criteria, assess reportability, capture source details, code events, request review, and document decisions.

54 What is a medically important event?

An event that may not meet standard seriousness outcomes but may jeopardize the patient or require intervention to prevent serious outcomes.

55 How do you answer “tell me about yourself” for PV?

Connect your science background, safety mindset, documentation skills, and PV knowledge. End with the role you want and how you add value.

56 Why do you want to work in pharmacovigilance?

A strong answer links patient safety, scientific analysis, regulatory responsibility, and structured teamwork. Avoid saying only “because PV has jobs.”

Scenario & HR Answers

Role-fit, deadlines, pressure, and fresher interview preparation.

57 How do you handle pressure and deadlines?

Explain prioritization, timeline tracking, early escalation, focused documentation, and communication with medical reviewers or leads.

58 What is your weakness for a PV interview?

Choose a manageable weakness, such as over-detailing narratives. Show control: checklist, timebox, feedback, and SOP alignment.

59 How would you handle a serious case received near deadline?

Confirm validity, assess reportability, inform the lead, prioritize critical data, document follow-up needs, perform QC, and submit according to SOP.

60 What should a fresher learn before a PV interview?

PV definitions, valid case criteria, ICSR workflow, MedDRA basics, seriousness vs severity, reporting concepts, GVP, and one clear case-processing example.

Source Notes for Accurate Answers

Use these references when updating the blog text and downloadable file.

WHO	Pharmacovigilance definition and public-health purpose.
ICH E2A / E2B(R3)	Clinical safety definitions and electronic ICSR standards.
EMA GVP	EU good pharmacovigilance practices, modules, signal management, PSURs, RMPs, and PSMF.
FDA MedWatch	FDA Form 3500A and safety reporting context.
MedDRA	Standardized medical terminology for regulatory safety communication.

Disclaimer: Always align interview answers with local regulation, company SOPs, product type, and current submission requirements.