Pharmacovigilance Case Processing Portfolio (Mock) – Trainee PV (ICSR & Safety Reporting)

Candidate: Pritamjit Konar | M.Sc. Biotechnology | GCP + CDM Trained.

1) Portfolio Overview -

This portfolio demonstrates readiness for an entry-level Pharmacovigilance role through simulated (mock) work: case triage & validity checks, ICSR data entry fields, follow-up query drafting, regulatory reporting readiness (CIOMS/MedWatch/XML awareness), EVWEB case retrieval log, and audit-ready documentation practices.
All samples are created for educational and portfolio purposes and do not contain any real patient-identifiable data.

2) Key Skills Demonstrated

- ICSR triage + initial validity assessment (Patient, Reporter, Suspect Product, Adverse Event).
- Structured, accurate data entry mindset + completeness checks (dates, seriousness, outcomes, meds).
- Regulatory timeline discipline using trackers (Intake → Data entry → QC → Submission readiness).
- Drafting follow-up queries to collect missing information in a professional tone.
- Audit readiness: clean case file index, version control, and documentation traceability.

3)Portfolio Projects (Mock)

*Project 1 — **ICSR Intake & Validity Triage Log (Excel)***

Objective: Practice how PV teams screen incoming cases and decide if they are valid and ready for processing.

Case ID	Source Type	Intake Date	Suspect Product Present?	AE Present?	Patient Identifiable?	Reporter Identifiable?	Validity Status	Priority	Next Action
PV-0001	Spontaneous (HCP)	2026-01-02	Yes	Yes	Yes	Yes	Valid	High	Start data entry + seriousness check.
PV-0002	Literature	2026-01-02	Yes	Yes	No	Yes	Not valid	Low	Draft follow-up: patient age/initials needed.
PV-0003	Clinical trial	2026-01-03	Yes	Yes	Yes	Yes	Valid	Medium	Enter + prepare follow-up for missing dates.

*Project 2 — **ICSR Data Entry Fields & QC Checklist (Excel/Word)***

Objective: Show structured thinking for accurate case entry and quality review before reporting.

Case ID	Patient Age/Sex	Suspect Product	AE Term	Onset Date	Seriousness	Outcome	Concomitant Meds	Data Entry Status	QC Status
PV-0001	45/M	Drug A	Rash	2026-01-01	Non-serious	Recovering	Cetirizine	Completed	Pass
PV-0003	62/F	Drug B	Elevated ALT	Missing	Serious (Hosp.)	Unknown	Metformin	In progress	Pending
PV-0004	29/F	Vaccine C	Fever	2025-12-30	Non-serious	Recovered	None	Completed	Pass

QC checks: Date logic (therapy start vs AE onset), duplicates, seriousness criteria filled, narrative consistency.

*Project 3 — **Follow-up Query Drafting & Tracking (Word + Excel)***

Objective: Demonstrate ability to request missing information politely and clearly.

Case ID	Missing Info	Follow-up Sent Date	Sent To	Status	Response Date	Closure Note
PV-0003	AE onset date + lab value units	2026-01-03	Site Coordinator	Open	—	Reminder planned in 3 days.
PV-0002	Patient age/initials	2026-01-03	Author/Journal contact	Sent	—	Awaiting reply.

One follow-up email template:

Subject: Follow-up request for safety case PV-0003
Body: Requesting missing AE onset date, relevant lab units, and outcome details to complete the ICSR as per reporting requirements**.**

*Project 4 — **Expedited Reporting Readiness Tracker (Excel)***

Objective: Show timeline ownership and compliance discipline (even as a trainee).

Case ID	Serious?	Listedness Known?	Expedited Candidate	Target Timeline (Internal)	Current Stage	Risk Flag	Action
PV-0003	Yes	Pending	Yes (review)	1–2 days triage/QC	Follow-up pending	High	Escalate the missing onset date.
PV-0001	No	NA	No	Standard	QC complete	Low	Archive as complete.

Project 5 — *EVWEB Case Retrieval Log (Excel) (basic mock)*

Objective: Demonstrate awareness of retrieving and tracking cases (company/non-company) and documenting actions.

Retrieval ID	Date	Case Type	Reference	Action Taken	Status
EV-001	2026-01-02	Company	Mock-Ref-101	Logged for review	Completed
EV-002	2026-01-03	Non-company	Mock-Ref-205	Flagged for screening	In progress

Project 6 — *Audit-Ready Case File Index (Excel)*

Objective: Show inspection mindset: complete, traceable documentation.

Case ID	Document Type	File Name	Version/Date	QC Status	Stored Location	Audit Ready
PV-0001	Source + narrative	PV-0001_Source_Narrative.docx	v1 / 2026-01-02	Pass	/PV/CaseFiles/PV-0001/	Yes
PV-0003	Follow-up	PV-0003_Followup_1.docx	v1 / 2026-01-03	Pending	/PV/CaseFiles/PV-0003/	No