Regulatory Affairs Portfolio (Mock)

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

Target role: Regulatory Affairs (Trainee/Associate)

1) Purpose -

Demonstrate readiness for trainee-level RA work through simulated deliverables: submission tracking, document checklists for different product types, regulatory intelligence logging, and project execution tracking.

2)Disclaimer: Self-learning mock portfolio only; no confidential company data and no real client dossiers are used.

3)Portfolio Projects (Mock)

*Project 1 — **Regulatory Submission Tracker (Applications / Renewals / Variations)***

Objective: Support regulatory submissions by tracking sequences, document readiness, review cycles, and health authority queries—exactly what a trainee supports.

Deliverables A: Submission Tracker (sample format).

Submission ID	Product Type	Country/Region	Submission Type	Milestone	Owner	Due Date	Status	Notes/Risks
SUB-001	Pharmaceutical	India	New application	Draft compilation	Self (Trainee)	2026-01-15	In progress	Awaiting final admin forms
SUB-002	Medical device	EU	Renewal	QA check	Self (Trainee)	2026-01-20	Pending	Need a labeling checklist
SUB-003	Food supplement	UK	Variation	Client review	Self (Trainee)	2026-01-25	Planned	Change summary required

*Project 2 — **Document Pack Checklist (Multi-Product: Pharma/Device/Cosmetic/Herbal/Food)***

Objective: Show documentation readiness across different regulated product categories.

Deliverables: Document Checklist (sample).

Product Type	Core Document	Version	Source	QC Check (Y/N)	Gap/Issue	Action
Pharmaceutical	Admin forms/cover letter	v1.0	Template	Y	—	Ready to compile
Medical device	Labeling/IFU checklist	v0.2	Draft	N	Missing warnings	Update from SME
Cosmetic	Ingredient compliance note	v0.1	Draft	N	References incomplete	Add citations
Herbal	Product composition summary	v1.0	Draft	Y	—	Finalize formatting
Food supplement	Claims substantiation note	v0.1	Draft	N	Evidence pending	Request data

Deliverable B: “Submission Packaging SOP (Mini)” – 1-page process: naming convention, versioning, QC steps, and handover notes.

*Project 3 — **Regulatory Intelligence (RI) Tracker + Knowledge Sharing Note***

Objective: Demonstrate a simple, repeatable process to capture regulatory updates, assess impact, and communicate to the team.

Deliverables: RI Tracker (sample).

RI ID	Source	Update Summary	Product Impact Area	Priority	Action Needed	Owner	Due Date	Status
RI-001	Agency site/newsletter	New guidance update (mock)	Labeling	High	Update checklist + inform lead	Self	2026-01-12	Open
RI-002	Internal memo (mock)	Template revision (mock)	Submissions	Medium	Replace the old template in the pack	Self	2026-01-14	Done

*Project 4 — **KPI Delivery Tracker + Stakeholder Communication Log***

Objective: Show project planning/execution aligned with KPIs and collaboration with leads/client teams.

Deliverable: Deliverables: KPI task tracker + stakeholder communication log (email/follow-up tracker)

Task ID	Project/Client (Mock)	Task	KPI Target	Due Date	Status	Dependency	Escalation/Note
KPI-001	Client A	Compile Module/Pack checklist	On-time delivery	2026-01-16	In progress	Pending inputs	Follow-up sent
KPI-002	Client A	QC check of submission set	Zero critical errors	2026-01-18	Planned	Draft completion	Use the QC checklist
KPI-003	Client B	Update tracker + weekly status	Weekly reporting	2026-01-19	Planned	—	Send to lead