# Health Operations New Associate Portfolio (Mock) – Life Sciences Regulatory Operations (Accenture)

**Candidate:** Pritamjit Konar | M.Sc. Biotechnology |

**Target role:** Health Operations New Associate

**1) Purpose -**

Demonstrate readiness for entry-level regulatory operations work by supporting electronic submission coordination, document readiness, lifecycle management tracking (CMC/amendments/annual reports/SPL), and routine team tasks with documentation discipline.

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

**3)Portfolio Projects (Mock)**

*Project 1 — **Electronic Submission Tracker (Original Filings + Lifecycle Management) (Excel)***

*Objective*: Coordinate essential documentation for global applications and track lifecycle submissions (CMC, ad-promos, amendments, annual reports, SPL) with status, due dates, and team handoff readiness.

Deliverables A: Submission Tracker (sample format).

| Submission ID | Submission Type | Product | Region | Key Documents | Status | Due Date | Owner/Team | Notes/QC Issues |
|---|---|---|---|---|---|---|---|---|
| ES-001 | Original Application | Pharma | India | Cover letter, admin forms, CMC | Document compilation | 2026-01-20 | Self (New Associate) | Awaiting final checklist |
| ES-002 | Annual Report | Medical Device | EU | SPL update, annual summary | QC check | 2026-01-25 | Self (New Associate) | Versioning complete |
| ES-003 | Amendment (CMC) | Food Supplement | US | Change summary, updated modules | Team review | 2026-01-30 | Self (New Associate) | Hyperlink check pending |

*Project 2 — **Document Readiness Checklist + QC Log (Multi-Submission Types) (Excel)***

*Objective:* Ensure submission-ready documents by maintaining checklists for electronic formats and performing basic QC (versioning, naming, completeness).

Deliverables: Document Checklist (sample).

| Doc ID | Document Name | Version | Naming Convention Met? | QC Check (Hyperlinks/Bookmarks) | Ready for Packaging? | Gap/Action |
|---|---|---|---|---|---|---|
| DOC-001 | Cover letter | v1.0 | Yes | Pass | Yes | — |
| DOC-002 | CMC module update | v0.2 | No | Fail (broken link) | No | Fix hyperlink |
| DOC-003 | SPL label | v1.1 | Yes | Pass | Yes | Ready for team |

*Project 3 — **Submission Timeline + Team Coordination Tracker (Excel)***

*Objective*: Support project planning with KPIs, deadlines, and team communication for on-time delivery in rotational shifts.

*Deliverables*: Timeline Tracker (sample).

| Task ID | Task | KPI | Due Date | Status | Team Lead Assigned | Dependency | Escalation |
|---------|------|-----|----------|--------|--------------------|------------|------------|
| TSK-001 | Compile filing pack | On-time | 2026-01-18 | In progress | Self | All docs QC'd | Follow-up email sent |
| TSK-002 | QC electronic format | Zero errors | 2026-01-22 | Planned | Self | Pack ready | Use SOP checklist |
| TSK-003 | Handoff to publishing | Team ready | 2026-01-24 | Planned | Self | QC pass | Notify supervisor |