Pharmaceutical GRC Workflow Architecture

Governance · Risk Management · Regulatory Compliance — End-to-End

01 — KEY STAKEHOLDERS & GOVERNANCE STRUCTURE

BOARD & EXECUTIVE LAYER

- Board of Directors
- Audit Committee
- CEO / CFO
- Chief Compliance Officer
- General Counsel
- Chief Risk Officer

FUNCTIONAL LEADERSHIP LAYER

- VP Regulatory Affairs
- VP Quality Assurance
- Medical Affairs Director
- Clinical Operations Head
- IT/Cybersecurity Lead
- Supply Chain Director

OPERATIONAL EXECUTION LAYER

- QC/QA Managers
- Pharmacovigilance Team
- Internal Audit
- Data Privacy Officers
- Manufacturing Supervisors
- External Auditors / CROs

REPORTING & ACCOUNTABILITY FLOW ▼

02 — END-TO-END GRC WORKFLOW PHASES

01 — Governance Framework Design
Strategy & Policy

- Define GRC charter & scope aligned to pharma operations
- Establish governance committees and RACI matrices
- Develop SOPs, policies & code of conduct
- Map regulatory obligations (FDA, EMA, ICH, CDSCO)
- Integrate ESG & ethics frameworks
- Set board reporting cadence & escalation paths

02 — Risk Identification & Assessment
Risk Intelligence

- Enterprise Risk Assessment (quality, clinical, supply, cyber)
- Pharmacovigilance & adverse event risk analysis
- Third-party & vendor due diligence risk mapping
- Data integrity & 21 CFR Part 11 gap analysis
- FMEA for manufacturing & critical processes
- Regulatory change intelligence monitoring

03 — Controls Implementation & Compliance
Control & Mitigation

- GMP/GCP/GLP control design & validation
- CAPA management system implementation
- Training & competency assurance programs
- Technology controls: eQMS, eReg, LMS platforms
- Supplier qualification & audit programs
- Anti-bribery (FCPA/UK Bribery Act) controls

04 — Monitoring, Audit & Reporting
Assurance & Oversight

- Continuous compliance monitoring & KPI dashboards
- Internal audit scheduling & execution
- Inspection readiness programs (FDA/EMA-ready)
- Regulatory submission tracking (NDA/IND/MAA)
- Management review & Board reporting
- Whistleblower & hotline incident tracking

05 — Remediation & Continuous Improvement
Close Loop & Evolve

- CAPA closure & effectiveness verification
- Deviation & OOS investigation resolution
- Regulatory response & commitment tracking
- GRC maturity benchmarking & gap closure
- Framework refresh for new regulations
- Lessons learned integration & culture evolution

↺ CONTINUOUS FEEDBACK LOOP — RISK INTELLIGENCE FEEDS BACK INTO GOVERNANCE DESIGN ↺

03 — KEY PERFORMANCE INDICATORS & REGULATORY COMPLIANCE LANDSCAPE

KPI DASHBOARD

≤2%
CAPA Overdue Rate (Target)
QUALITY · MONTHLY

98%+
GxP Training Completion Rate
COMPLIANCE · QUARTERLY

72hr
Adverse Event Reporting TAT
PHARMACOVIGILANCE · CONTINUOUS

100%
Critical Audit Findings Closed On Time
AUDIT · BI-ANNUAL

0
Class I Recalls in Reporting Period
QUALITY RISK · ANNUAL TARGET

≤30d
Deviation Investigation Closure
OPERATIONS · ROLLING

95%+
Supplier Qualification Score
SUPPLY CHAIN · ANNUAL

<1%
OOS/OOT Incident Rate
LABORATORY · MONTHLY

REGULATORY COMPLIANCE LANDSCAPE

FDA — US FDA — 21 CFR Parts 11, 210, 211, 312
cGMP, electronic records, IND requirements, drug manufacturing standards

EMA — EMA — EU GMP Annex 11, 15, 21
Computerised systems, qualification, validation, GDP directive 2013/C 343/01

ICH — ICH Q7/Q8/Q9/Q10/Q12/E6
Active pharma ingredients, pharmaceutical development, quality risk management, GCP

ISO — ISO 9001 / 14971 / 37001 / 27001
Quality management, medical device risk, anti-bribery, information security

GDPR — GDPR / HIPAA / DPDP Act 2023
Clinical trial data, patient privacy, cross-border data transfers, consent management

CDSCO — CDSCO — Drugs & Cosmetics Act
Indian drug manufacturing, import/export licensing, Schedule M compliance, pharmacovigilance

LOW LIKELIHOOD   MEDIUM LIKELIHOOD   HIGH LIKELIHOOD   HIGH

IMPACT / SEVERITY

| Supply Disruption | Data Integrity Breach | Patient Safety Event |

MEDIUM | Vendor Non-compliance | Audit Observation |

Regulatory Warning Letter   LOW   Minor SOP Deviation

Training Gap   Documentation Error

PHASE 01 · GOVERNANCE
Policy issuance logged, version-controlled, and approved via e-signature in document management system. Board sign-off archived.

PHASE 02 · RISK
Risk register entries time-stamped with owner, assessment methodology, inherent vs residual ratings, and review history.

PHASE 03 · CONTROLS
CAPA records capture root cause, action plan, responsible party, target date & verification evidence per 21 CFR Part 11.

PHASE 04 · MONITORING
Audit findings logged in eQMS with observation classification, response timeline, and regulatory inspector access trails.

PHASE 05 · REMEDIATION
Effectiveness checks verified, closure criteria met, regulatory commitments tracked against submission deadlines.

04 — TECHNOLOGY ENABLERS & GRC TOOLING

⚙	📋	🔍	🛡	📊	🎓
eQMS Platform	**Regulatory Submission Tracker**	**Risk Management Software**	**Data Integrity & Audit Logs**	**GRC Dashboard & BI**	**LMS / Training Platform**
QUALITY CONTROL	COMPLIANCE	RISK INTELLIGENCE	21 CFR PART 11	REPORTING	COMPETENCY

EXPERT GRC ADVISORY — PHARMA SECTOR

Ready to Build a Resilient GRC Framework?

REDE Consulting delivers end-to-end GRC transformation for pharmaceutical and life sciences organisations — from regulatory strategy and risk architecture to audit readiness and compliance culture. Let's design a framework built for your specific regulatory landscape.

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