

Apichem Laboratories Private Limited

RISK MANAGEMENT POLICY

1. Objective

The objective of this Risk Management Policy is to ensure that **Apichem Laboratories Private Limited** (“the Company”) has a structured, continuous process of identifying, assessing, mitigating, and monitoring risks across its operations. This framework ensures sustainable business growth, regulatory compliance, product quality, and patient safety.

2. Scope

This policy applies to:

- Research & Development (R&D)
- Active Pharmaceutical Ingredients (API) and Formulation plants
- Quality Assurance (QA) and Quality Control (QC)
- Regulatory Affairs and Pharmacovigilance
- Sales, Marketing, and Distribution (Domestic & International)
- Finance, Treasury, and Legal
- Information Technology (IT) & Data Integrity
- Environment, Health & Safety (EHS)
- Human Resources

3. Risk Categories & Mitigation Measures

A. Business Risks

1. **Concentration Risk** – Diversify product portfolio, markets, and customers.
2. **Competition Risk** – Continuous innovation, strong regulatory compliance, and customer-centric approach.
3. **Pricing Risk** – Regular cost optimization, yield improvement, and value engineering.
4. **International Operations Risk** – Monitor geopolitical risks, comply with local laws, hedge forex, and use insurance.
5. **Intellectual Property Risk** – Pre-commercialization patent checks, in-house IPR cell, and collaborations.
6. **Employee Turnover Risk** – Robust HR policies, career development, training, and retention programs.

B. Regulatory & Compliance Risks

- Compliance with:
 - **Drugs & Cosmetics Act, 1940 and Rules, 1945**
 - **Drugs and Magic Remedies Act, 1954**
 - **Schedule M (GMP), WHO-GMP, US FDA, EMA, MHRA, TGA, ANVISA requirements**
 - **ICH Guidelines (Q7–Q10)**
 - **Pharmacovigilance Regulations (PV Rules, EU GVP, US FDA FAERS)**

- **21 CFR Part 11** – electronic records and data integrity

- Mitigation: Dedicated regulatory teams, frequent audits, training, and proactive engagement with authorities.

C. Quality Risks

- Risks: Product recalls, contamination, data integrity issues.
- Mitigation: SOP compliance, automation, periodic quality audits, and strong CAPA systems.

D. Financial Risks

1. **Credit Risk** – Strict credit policies, customer due diligence.
2. **Forex & Treasury Risk** – Regular monitoring, forward contracts, and hedging.
3. **Legal Risk** – Thorough contract vetting, external legal counsel, litigation management.

E. Operational Risks

- Manufacturing downtime, raw material shortages, supply chain bottlenecks.
- Mitigation: Preventive maintenance, vendor diversification, business continuity planning.

F. Reputational Risks

- Media scrutiny, regulatory warnings, or product bans.
- Mitigation: Transparent communication, compliance culture, CSR initiatives.

G. Technology & Cybersecurity Risks

- ERP failures, cyberattacks, loss of R&D data.
- Mitigation: Robust IT security, backups, periodic penetration testing, compliance with data protection norms.

H. Environmental, Health & Safety (EHS) Risks

- Non-compliance with **Factories Act, 1948, Environment Protection Act, 1986, Hazardous Waste Rules.**
- Mitigation: Regular safety audits, effluent treatment, employee safety training, occupational health monitoring.

4. Risk Management Process

- a) **Identification** – Functional heads identify potential risks.
- b) **Assessment** – Likelihood and impact classified (High/Medium/Low).
- c) **Mitigation** – Action plans developed (avoid, reduce, transfer, or retain).
- d) **Monitoring** – Periodic reporting of Key Risk Indicators (KRIs).
- e) **Review** – Annual review of the policy and lessons from past incidents.

5. Roles & Responsibilities

- a) **Board of Directors** – Overall responsibility for risk oversight.
- b) **Managing Director/CEO** – Implementation of risk management strategy.
- c) **Chief Risk Officer / Senior Management** – Coordinate risk activities across functions.
- d) **Functional Heads** – Identify and mitigate risks within departments.
- e) **Employees** – Adherence to SOPs, reporting risks, maintaining compliance culture.

6. Reporting

- a) **Quarterly** – Management reviews major risks.
- b) **Annually** – Board reviews overall risk management framework.
- c) **Immediate Reporting** – Critical risks (e.g., product recall, regulatory action) escalated to the Board.

7. Policy Review

This policy shall be reviewed and updated as required in line with changes in laws, regulations, or business environment.