

Pharma, Chemicals & Life Sciences — 104 tools

All tools · at-a-glance descriptions · Generated 15 Oct 2026

This is the full list of AiSevak tools in this industry, each with a short description of what it produces. Open any tool on aisevak.in to run it.

Manufacturing & GMP

GMP Implementation Guide

Produces a GMP implementation roadmap for a manufacturing unit per revised Schedule M — area by area (premises and facility, personnel, documentation, production, quality control, validation) with requirements and gap-closure actions. Use this to plan or upgrade GMP compliance. For an inspection-readiness check use the GMP Self-Audit Checklist.

Manufacturing SOP Writer

Writes a GMP manufacturing SOP for a specific process — purpose, scope, responsibilities, step-by-step procedure, in-process checks, documentation (batch-record entries) and references. Use this to standardise a production process compliantly. For the batch record structure use the Batch Manufacturing Record (BMR) tool.

Batch Manufacturing Record (BMR)

Builds a Batch Manufacturing Record (BMR) structure — product and batch details, materials, equipment, step-wise process with checks and sign-offs, yields, deviations and reconciliation — plus critical controls (line clearance, weighing, in-process checks). Use this to structure a compliant batch record. It must match your approved master formula and be QA-approved.

Cleaning Validation Protocol

Builds a cleaning validation protocol structure — worst-case product, acceptance criteria (MACO), sampling (swab and rinse), analytical method and three validation runs, with the protocol and report documentation. Use this to prevent and prove control of cross-contamination on shared equipment. Validation must be executed and QA-approved per GMP.

Process Validation Protocol

Builds a process validation protocol structure — approach (prospective, concurrent), critical process parameters, critical quality attributes, three consecutive batches, sampling and testing, and acceptance criteria, with protocol and report documentation. Use this to demonstrate a consistent, capable process. Validation must follow your VMP and be QA-approved.

Equipment Qualification (IQ/OQ/PQ)

Builds an equipment qualification (DQ/IQ/OQ/PQ) structure — design, installation, operational and performance qualification checks — with protocol and report documentation. Use this to qualify a piece of equipment the GMP way. Execute and approve per your validation master plan.

GMP Self-Audit Checklist

Builds a GMP self-audit checklist — area by area (facility, documentation, production, QC, warehouse, personnel, validation) with checks, common observations and corrective-action readiness. Use this to be inspection-ready for CDSCO and customer audits. For a full GMP implementation roadmap use the GMP Implementation Guide.

Deviation & CAPA Report

Produces a deviation and CAPA report — description, classification (minor/major/critical), impact assessment on product quality, root cause, and corrective and preventive actions. Use this to document a deviation and fix its root cause. Deviations need QA assessment and approval.

Change Control Procedure

Writes a change control procedure — request, impact assessment, classification, approvals, implementation, verification and closure — with a regulatory-impact view (whether it needs notification or approval). Use this to manage a change without risking quality or compliance. Changes need QA and regulatory assessment.

Quality Control & Assurance

QC Laboratory SOP

Writes a QC laboratory SOP for a test or lab process — purpose, procedure (sample handling, testing, calculations, reporting), controls (reference standards, calibration, data integrity) and records — with ALCOA+ data-integrity principles. Use this for reliable, compliant lab testing. Align to your pharmacopoeia methods and GMP.

Stability Study Protocol

Builds a stability study protocol structure — conditions (long-term and accelerated per zone IVb), time points, parameters, acceptance criteria and packaging — and how the data supports the shelf life. Use this to establish shelf life with data. Follow ICH and CDSCO stability requirements for India.

Analytical Method & Validation

Builds an analytical method validation structure — specificity, linearity, accuracy, precision, LOD/LOQ, robustness and system suitability — with acceptance criteria and protocol/report documentation. Use this to validate a test method per ICH Q2. For the routine testing SOP use the QC Laboratory SOP.

Certificate of Analysis (COA)

Builds a Certificate of Analysis (COA) structure — product and batch details, a tests-and-specifications table with result placeholders, the conforms/does-not-conform conclusion and authorised-by signature. Use this to produce clear, complete COAs. Results must come from validated testing and QA release.

OOS / OOT Investigation

Builds an OOS/OOT investigation framework — Phase 1 lab investigation, Phase 2 full investigation, root cause, retest and resample rules, and impact and disposition — with an investigation report. Use this to investigate out-of-specification results properly. Follow your OOS SOP and GMP guidance with QA approval.

Quality Manual Builder

Drafts a pharmaceutical quality manual structure — quality policy, the pharmaceutical quality system elements (documentation, change, deviation, CAPA, complaints, recall, self-inspection) and responsibilities. Use this to document your quality management system. Align it to your PQS and Schedule M.

Document Control & Data Integrity

Drafts a document control and data integrity procedure — document control (numbering, approval, revision, distribution, obsolete), record control (retention, archival) and data integrity (ALCOA+, audit trails, access controls, backups). Use this to control documents and protect data per GMP and data-integrity guidance.

Sampling Plan Builder

Builds a sampling plan — by stage (raw material, in-process, finished) the sampling basis, quantity and tools/hygiene — with sampling records. Use this to sample so the sample represents the batch, per pharmacopoeia and GMP requirements.

Quality System Audit

Builds a quality system self-audit — area by area (documentation, deviation and CAPA, change control, complaints, recall, training, data integrity) with checks, a Good/Fair/Poor scorecard and priority fixes. Use this to audit your quality system end to end. For a facility-focused GMP audit use the GMP Self-Audit Checklist.

Regulatory & Product Registration

CDSCO Regulatory Primer

Provides a CDSCO and drug-regulation primer — the framework (Drugs and Cosmetics Act and Rules, central CDSCO and state licensing authorities, new drugs rules), the key approvals (manufacturing licence, product permission, import, new drug approval) and the authorities (CDSCO, state FDA, DCGI). Use this to get oriented. Regulations are technical, so engage a regulatory professional.

Drug Manufacturing Licence Guide

Explains drug manufacturing licence requirements — the application to the state licensing authority, premises and equipment, competent technical staff, inspection and grant — with awareness of the relevant forms (e.g. 25/28) and prerequisites (GMP facility, qualified staff). Use this to get your manufacturing licence. Confirm current forms and requirements with your state FDA.

Product Permission / Registration

Explains product permission and registration — product permission from the licensing authority, new drug approval if applicable, and the documents (formulation, specs, stability, method) — with a note on when central approval is needed. Use this to register a product for manufacture. Requirements depend on the product category; confirm with a regulatory expert.

Regulatory Dossier Structure

Builds a regulatory dossier structure — administrative, quality (CMC), and safety and efficacy as applicable, in CTD or country format — with the key documents (specs, methods, stability, BE where needed) and domestic-vs-export format differences. Use this to structure a submission dossier. Requirements vary by market; engage regulatory experts.

Drug Labeling Compliance

Explains drug labeling compliance — required particulars (generic and brand name, composition, batch, mfg and expiry, MRP, storage, schedule symbol and warnings, manufacturer, licence number), package insert where required, and scheduled-drug specifics (Rx symbol, warnings). Use this for compliant labels and inserts per the Drugs and Cosmetics Rules.

Regulatory Strategy Planner

Builds a regulatory strategy for a product launch — the approvals needed by market, sequence, timelines, data requirements and risks, with prioritisation across markets and products. Use this to plan the regulatory path for a launch. Engage regulatory affairs professionals for execution.

Import Licence & Registration

Explains drug import licence and registration for India — the registration certificate and import licence, authorised agent, documents and CDSCO involvement — with the documents needed (manufacturer details, GMP, product info). Use this to import drugs or materials legally. Drug import is tightly regulated; engage a regulatory professional.

Schedule Classification Guide

Explains drug schedule classification under the Drugs and Cosmetics Rules — Schedule H, H1, X and others, prescription and sale conditions — with the implications (labeling, sale, record-keeping) and how to determine your product schedule. Use this to know your drug schedule and its rules. Confirm the exact schedule and conditions for your product.

Regulatory Compliance Audit

Builds a regulatory compliance self-audit — area by area (licences, product permissions, labeling, records, reporting) with checks and evidence, a Compliant/Gap/Critical scorecard and priority fixes. Use this to self-check regulatory compliance against the Drugs and Cosmetics Rules.

Chemicals & Safety

Chemical Safety Guide

Builds a chemical safety guide for a pharma or chemical unit — hazard identification, handling, PPE, storage, exposure control and spill response — with MSIHC (Manufacture, Storage and Import of Hazardous Chemicals Rules) awareness and training. Use this to handle chemicals safely and legally. For an SDS document use the Safety Data Sheet Builder.

Safety Data Sheet (SDS) Builder

Builds a GHS-aligned Safety Data Sheet (SDS) structure — all 16 sections from identification and hazards through handling, storage, exposure controls, toxicology, disposal, transport and regulatory info — with GHS classification and labelling notes. Use this to structure a compliant SDS. Content must be technically accurate and GHS-compliant.

Hazardous Material Handling SOP

Writes a hazardous material handling SOP — receiving, storage segregation, transfer, PPE, controls and disposal — with emergency response (spill and exposure) and training. Use this for safe handling of hazardous materials per MSIHC and safety norms.

Chemical Storage & Segregation

Designs a chemical storage and segregation plan — segregation by hazard class, incompatibilities, ventilation, spill containment, flammable stores and quantity limits — with safety systems (fire, detection, bunding). Use this to store chemicals safely and compliantly per MSIHC and fire norms.

Effluent & Emission Compliance

Explains effluent and emission compliance for a pharma or chemical unit — effluent (ETP, ZLD where mandated, discharge norms, SPCB consent), emissions (stack and process, control equipment), hazardous waste (authorisation and disposal) and monitoring records/returns. Use this to meet pollution norms. Meet your SPCB consent conditions and applicable rules.

Chemical Manufacturing Licences

Identifies the licences for a chemical or API manufacturing unit — factory licence, pollution consent, hazardous chemical, PESO/explosives if applicable, drug licence for API, fire — with the authority and when each is needed, in priority order. Use this to know the licences for chemical manufacture. Requirements vary by product and state; confirm locally.

Spill & Emergency Response Plan

Builds a spill and emergency response plan — scenarios (spill, fire, exposure, release), scenario-wise response actions, resources (spill kits, PPE, showers) and emergency contacts (fire, hospital, pollution board). Use this to be ready for chemical emergencies, aligned to on-site emergency plan requirements for hazardous units.

Chemical Safety Audit

Builds a chemical safety self-audit — area by area (storage, handling, PPE, emergency, effluent and emissions, records) with checks, a Good/Gap/Critical scorecard and priority fixes. Use this to self-audit chemical safety against MSIHC and safety norms.

Fire Safety & NOC Guide

Explains fire safety and NOC for a pharma or chemical unit — extinguishers, hydrants, detection, flammable-area protection, exits and drills — with the fire-department NOC process and renewal, and the high-risk activities (solvent and flammable handling). Use this for fire safety and the NOC. Confirm with your fire department.

Distribution & Supply Chain

Pharma Distribution Setup

Produces a pharma distribution setup guide — wholesale drug licence, premises and cold storage, competent person, systems and the supplier/customer network — with the licence (Form 20B/21B) awareness and operations (procurement, storage, sales, returns). Use this to set up wholesale drug distribution. Confirm current licensing with your state FDA.

C&F / Distribution Agreement

Drafts a carrying and forwarding (C&F) or distribution agreement — a clause-by-clause draft covering territory, storage and handling, margins and charges, stock and returns, expiry handling, compliance and licences, payment, and term and termination. Use this to formalise a C&F agent or stockist arrangement. Have it reviewed by a lawyer.

Cold Chain Management Plan

Builds a cold chain management plan — storage, temperature monitoring, transport, excursion handling and validation — with equipment (cold rooms, data loggers, reefer) and temperature-log records. Use this to protect temperature-sensitive products per GDP and storage requirements.

Pharma Inventory Management

Builds a pharma inventory management approach — batch and expiry tracking, FEFO, near-expiry handling, reorder and storage conditions — with expiry control (alerts, returns) and controls (reconciliation, temperature). Use this to control stock, expiry and batches per GDP. For retail-pharmacy-specific control use the Pharmacy Inventory & Expiry Control tool.

Batch Traceability System

Designs a batch traceability system — batch capture at each stage, customer-batch linkage and quick recall trace — with records (sales with batch, returns) and recall readiness (trace forward and backward). Use this to trace every batch through the chain. For the recall process itself use the Product Recall Plan.

Product Recall Plan

Builds a product recall plan — classification, decision, notification to authorities and trade, retrieval, reconciliation, disposal and an effectiveness check — with communication (trade and regulator) and records. Use this to recall products quickly and completely. Follow CDSCO recall guidelines and notify authorities.

Serialisation & Track-Trace Guide

Explains serialisation and track-and-trace for Indian pharma — barcoding on primary, secondary and tertiary packs, DGFT track-trace for exports and domestic requirements for top brands — with data upload portal awareness and implementation (systems and printing). Use this to meet coding and track-trace requirements. Confirm current DGFT and CDSCO requirements.

Good Distribution Practice SOP

Writes Good Distribution Practice (GDP) SOPs for a pharma distributor — receipt and storage, temperature control, picking and dispatch, returns, recalls, expiry and documentation — with quality (competent person, self-inspection). Use this to run GDP-aligned distribution operations per your licensing conditions.

Supply Agreement Draft

Drafts a pharma supply agreement — a clause-by-clause draft covering products and specs, pricing, quality and COA, delivery, batch and expiry, returns, liability and recall, and term and termination, with schedules. Use this for supply terms with buyers or institutions. Have it reviewed by a lawyer.

Pharmacy Retail

Retail Pharmacy Setup Guide

Produces a retail pharmacy setup guide — retail drug licence, registered pharmacist, premises and storage, GST, systems and opening stock — with the licences (retail drug licence, pharmacist registration) and operations (procurement, sales, records). Use this to open a compliant retail pharmacy. For the licence specifics use the Pharmacy Licence Guide.

Pharmacy Licence Guide

Explains retail drug licence requirements — the application, registered pharmacist, premises and storage, inspection, grant and renewal — with the documents (pharmacist registration, premises proof) and conditions (storage, records, pharmacist presence). Use this to get your retail drug licence. Confirm forms and requirements with your state FDA.

Pharmacy Operations SOP

Writes retail pharmacy operations SOPs — procurement and receipt, storage, dispensing against prescription, billing, records, expiry and returns — with compliance (Schedule H/H1 dispensing, pharmacist supervision, prescription records). Use this to run the pharmacy safely and compliantly per the Drugs and Cosmetics Rules.

Schedule H / H1 Dispensing Guide

Explains Schedule H and H1 dispensing compliance for a pharmacy — prescription requirement, the H1 register for specified drugs (what to record and retention) and the pharmacist role — with NDPS awareness for controlled substances where applicable. Use this to dispense prescription drugs correctly and maintain required registers.

Pharmacy Inventory & Expiry Control

Builds an inventory and expiry control system for a retail pharmacy — batch and expiry tracking, FEFO, near-expiry returns, reorder and fast/slow movers — with expiry management (alerts, returns to distributor) and shrinkage controls. Use this to control stock, expiry and shrinkage in the store.

Pharmacy Billing & GST Guide

Explains billing and GST for a retail pharmacy — GST invoicing, drug rates, batch and expiry on the bill, and records — with GST-rate awareness on medicines and composition-vs-regular considerations, plus sales and prescription records. Use this to bill correctly with GST and records. Confirm current GST rates with a professional.

Online Pharmacy Compliance

Explains online pharmacy (e-pharmacy) compliance considerations — valid drug licence, registered pharmacist, prescription verification, no dispensing of restricted drugs online and data privacy — with the evolving regulatory status and operations (prescription handling, delivery). Use this to sell medicines online within the rules. E-pharmacy rules are evolving; take regulatory and legal advice.

Pharmacy Compliance Audit

Builds a compliance self-audit for a retail pharmacy — area by area (licence and pharmacist, storage, dispensing and registers, expiry, records, billing) with checks, a Compliant/Gap/Critical scorecard and priority fixes. Use this to self-audit your pharmacy against the Drugs and Cosmetics Rules.

Marketing & Compliance

Pharma Marketing Code Guide

Explains the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) — permissible promotion, restrictions on gifts and hospitality, samples and claims substantiation — with prohibited practices (inducements, misleading claims) and a compliance setup (policy, training, records). Use this to market ethically. For an operational compliance framework use the Marketing Compliance Setup tool.

Medical Rep (MR) Management

Builds a medical representative (MR) management approach — territory and coverage, call planning, reporting and targets — with productivity metrics (calls, coverage, prescriptions) and UCPMP-aligned compliance. Use this to run an effective, compliant field force. For incentives use the Field Force Incentive Scheme.

Promotional Material Reviewer

Reviews promotional material against a compliance checklist — claim substantiation, approved indications only, balanced information, references, no misleading content and prescribing information — with prohibited elements (unapproved claims, unsupported comparatives). Use this to vet promo material before use. Claims must be substantiated and UCPMP-compliant; get medical and legal sign-off.

Product Training Kit

Builds a product training kit for the field force — product knowledge (composition, indications, dosage, safety), positioning (approved messaging), objection handling (within approved claims) and an assessment. Use this to train MRs on a product. Keep to approved indications and UCPMP.

Brand Marketing Plan

Builds a brand marketing plan for a pharma product — positioning, target specialists, key messages (approved claims), channels (MR, KOL, digital, CME) and tactics — with UCPMP-aligned compliance. Use this to plan a compliant brand strategy. Keep to approved claims and UCPMP.

Marketing Compliance Setup

Builds a marketing compliance framework — policy, material-approval process, expense controls, HCP-interaction rules, records, training and audits — with approval-log documentation. Use this to build UCPMP compliance into your marketing operations. Take legal advice. For the UCPMP rules themselves use the Pharma Marketing Code Guide.

KOL Engagement Plan

Builds a KOL engagement plan within compliance limits — identification, scientific engagement, advisory, speaker programs and CME — with compliance (fair market value, documentation, UCPMP, no inducement) and legitimate scientific value exchange. Use this to engage key opinion leaders compliantly.

Awareness Campaign Plan

Builds a disease awareness campaign plan — awareness objective, audience, channels and educational content, with no brand promotion to patients for prescription drugs. Use this to run responsible disease awareness. Direct-to-consumer advertising of prescription drugs is restricted, so keep it educational and compliant.

Pharma Digital Marketing Guide

Builds a pharma digital marketing guide within compliance — HCP digital engagement, e-detailing, patient education (non-promotional for Rx) and CME — with compliance (no Rx DTC promotion, approved content, data privacy) and channels. Use this to reach doctors and patients compliantly online. Follow UCPMP and Rx advertising restrictions.

Exports & Trade

Pharma Export Setup Guide

Guides pharma export setup — IEC, Pharmexcil RCMC, WHO-GMP and COPP, product registration in target markets and AD code — with regulated-vs-semi-regulated market requirements and getting-started steps. Use this to start exporting pharmaceuticals. Confirm current DGFT, CDSCO and target-market requirements.

Pharma Export Documentation

Lists pharma export documentation — commercial invoice, packing list, shipping bill, COA, COPP, free sale certificate, product registration and track-trace — with the quality documents (COA, stability where needed). Use this to get export paperwork right. Confirm with your CHA and target-market requirements.

Overseas Product Registration

Outlines overseas product registration for an exporter — dossier (CTD), local agent, fees, timelines and GMP evidence — with market-specific variations and the documents to prepare. Use this to register products in export markets. Each country has its own process; engage regulatory experts.

WHO-GMP Certification Guide

Explains WHO-GMP certification for a manufacturer — what it is, its benefit for exports, the application to the state licensing authority and the inspection — with prerequisites (GMP compliance, documentation) and the process. Use this to get WHO-GMP for export credibility. Confirm the current process with your state licensing authority.

COPP / Free Sale Certificate Guide

Explains the Certificate of Pharmaceutical Product (COPP, WHO format), free sale certificate and market standing certificate — their purpose (needed for overseas registration) and the application process to the licensing authority. Use this to get the certificates buyers ask for. Confirm the process with your state licensing authority.

Pharma Export Costing

Builds a pharma export costing — a cost sheet (product cost, packaging and labeling, documentation, freight, insurance, margin) with prices by Incoterm (FOB, CIF) and RoDTEP/drawback incentive awareness. Use this to price exports profitably. Verify freight and incentives. For a domestic product cost sheet use the Product Costing Calculator.

Pharma Export Contract

Drafts a pharma export contract — a clause-by-clause draft covering products and specs, quality and COA, price and Incoterm, payment (LC), delivery and shelf-life, regulatory responsibility, liability and recall, and governing law and arbitration. Use this for a solid export supply contract. Have it reviewed by an export or legal expert.

Importer / Market Compliance Guide

Explains importer and market compliance for an exporter — GMP evidence, product registration, labeling and language, stability zone and testing — with the documentation and preparation needed. Use this to meet what your export market demands. Requirements vary by country; confirm with the buyer and regulatory experts.

Pharmexcil & Export Benefits Guide

Explains Pharmexcil membership and export benefits — RCMC, market support and promotion — with incentive awareness (RoDTEP, drawback) and benefits (market access, delegations, information). Use this to use council support and incentives. Confirm current membership and incentive details.

Finance & Business

Pharma Business Case / Loan Note

Writes a business case / loan note for a pharma venture — executive summary, the investment with line items, projected financials (revenue, margin, payback, ROI), funding ask and risks with mitigation (regulatory, market, quality). Use this to raise funding for a pharma venture. Projections are illustrative; validate before submission.

Pharma Business P&L Builder

Builds a structured P&L for a pharma business — line-by-line revenue against material, manufacturing, QC and QA, marketing and field force, distribution and other costs — with key ratios (material %, gross margin) and insights. Use this to see your business profitability clearly. It complements, not replaces, your accountant.

Product Costing Calculator

Builds a product costing sheet for a formulation — API and excipients, packing, conversion, QC and overhead to a total cost per unit — with a margin and pricing note (DPCO awareness for scheduled drugs). Use this to cost a formulation accurately. Use actual rates and check DPCO for scheduled drugs.

Drug Pricing & DPCO Guide

Explains drug pricing and DPCO — scheduled-drug price ceilings by NPPA, the non-scheduled annual increase cap, and the National List of Essential Medicines — with compliance (ceiling price, price display, revisions) and pricing freedom for non-scheduled drugs within the cap. Use this to price within drug price control. DPCO and NPPA rules change; confirm current ceiling prices.

Pharma GST Guide

Explains GST for a pharma business — rate awareness (medicine slabs, APIs, life-saving drugs), job-work (loan licence and job-work provisions), input credit and GST returns. Use this to understand GST on medicines, APIs and job work. GST rates change; confirm with a tax professional.

Pharma KPI Dashboard

Defines a practical KPI set and review cadence for a pharma business — for each KPI the formula, why it matters and a benchmark hint — covering batch yield, right-first-time, OOS rate, on-time delivery, field-force productivity, prescriptions, expiry/returns and working capital. Use this to build a dashboard. Set targets from your own history.

Working Capital Planner

Builds a working capital plan for a pharma business — the drivers (inventory of RM/WIP/FG, receivables, expiry returns, payables), cash levers (faster collection, inventory control, supplier terms) and financing (working capital, bill discounting). Use this to manage cash across long pharma cycles. Validate with your books.

Product Margin Analyzer

Analyses product-level margins across your portfolio — per product the price, cost, margin % and a Push / Reprice / Review verdict — with mix actions and a DPCO note (check scheduled-drug ceilings). Use this to find your most profitable products and act on the mix.

HR & Training

Pharma Hiring Kit

Creates a hiring kit for a pharma role — a job description (title, responsibilities, requirements like B.Pharm/M.Sc and experience, salary-range hint), where to hire and an interview guide (technical, GMP awareness). Use this to hire production, QC, QA and field staff. For a training program use the GMP Training Program.

GMP Training Program

Designs a GMP training program — modules (GMP basics, documentation and data integrity, hygiene and gowning, deviation and CAPA, safety) with frequency — and training records and effectiveness. Use this to build a GMP-aware workforce. GMP training is a regulatory requirement; maintain records. For SOP-specific training use the SOP Training & Assessment tool.

SOP Training & Assessment

Builds an SOP training and assessment approach — role-based SOP assignment, read-and-understand, on-the-job training, assessment and requalification on revision — with a training matrix. Use this to ensure staff follow SOPs correctly. Maintain training records per GMP.

Field Force Incentive Scheme

Designs a field force incentive scheme — basis (sales, coverage, new prescriptions, compliance) and payout slabs — with guardrails against unethical inducement to prescribers. Use this to motivate the field force compliantly. Ensure it does not encourage UCPMP violations.

Shift Roster Planner

Designs a shift roster for a pharma unit — by area (production, QC, packing) the shift, manpower and coverage — meeting labour norms (hours, weekly off). Use this to plan shifts for production and QC. Follow Factories Act rules.

Conduct & Compliance Policy

Drafts a conduct and compliance policy for a pharma company — principles (data integrity, quality-first, UCPMP compliance, confidentiality, safety), prohibited practices (data falsification, unethical promotion) and consequences. Use this to set ethics and conduct for pharma staff, aligned to GMP, UCPMP and law.

Attendance & Leave Policy

Drafts an attendance and leave policy for a pharma business aligned to the Factories or Shops and Establishment Act — full policy text, leave types (casual, sick, earned, weekly off, festival) with entitlement and rules, and field-staff attendance. Use this for a fair attendance system. Align the specifics to your state rules.

Skill & Qualification Matrix

Builds a skill and qualification matrix for a pharma unit — by role or operation the required qualification, proficiency and training status — with a gap analysis. Use this to track competencies and coverage and ensure trained staff for GMP operations. For the training itself use the GMP Training Program.

R&D & Product Development

Formulation Development Guide

Outlines a formulation development approach — preformulation, formulation trials, excipient selection, process, scale-up and stability — with Quality-by-Design awareness and a development report. Use this to develop a stable, manufacturable product. Formulation development needs qualified scientists and studies. For the project timeline use the R&D Project Plan.

R&D Project Plan

Builds an R&D project plan — phased (feasibility, development, scale-up, stability, filing) with activities, durations, milestones and risks. Use this to plan a product development project. Adapt it to your product and regulatory pathway. For the development method use the Formulation Development Guide.

Bioequivalence Study Guide

Explains bioequivalence (BE) study requirements for a generic — when BE is required, study design, CRO and ethics — with the CDSCO and target-market regulatory requirements and timeline/cost awareness. Use this to understand BE for filing. BE studies need qualified CROs and regulatory guidance.

Patent & IP Strategy

Outlines patent and IP strategy considerations for a pharma product — patent landscape, freedom to operate, patent expiry, non-infringing routes and own IP — with generic-launch timing vs patent expiry and infringement-risk caution. Use this to navigate patents. Engage a patent attorney for FTO and strategy.

Technology Transfer Protocol

Builds a technology transfer protocol structure — product and process knowledge, documentation, scale-up, validation and analytical transfer — with a transfer protocol and report. Use this to transfer a product from R&D to production or to a CMO. Tech transfer needs QA oversight and validation.

Nutraceutical Development Guide

Outlines nutraceutical development under FSSAI — formulation, permitted ingredients and limits, claims rules and labeling — with the regulatory frame (FSSAI nutraceutical regulations, no drug claims) and GMP for food supplements. Use this to develop supplements compliantly. Follow FSSAI nutraceutical rules and avoid drug claims.

Cosmetic Product Development

Outlines cosmetic product development and compliance — formulation, safety, stability and permitted ingredients — with the regulatory frame (Cosmetics Rules, manufacturing licence, labeling, no drug claims) and ingredient safety/testing. Use this to develop cosmetics compliantly. Follow the Cosmetics Rules and avoid drug claims.

R&D Documentation System

Designs an R&D documentation system — lab notebooks, development reports, method and stability data, and traceability — with data integrity (ALCOA+, controlled records) and IP support (records to support patents and filings). Use this to document development for filings and IP. Maintain good documentation for regulatory and IP purposes.

Contracts & Compliance

Loan Licence Agreement

Drafts a loan licence manufacturing agreement — a clause-by-clause draft covering scope and products, use of licence and premises, quality and GMP responsibility, materials, batch release, IP and confidentiality, liability, and term and termination — with a note on loan-licence regulatory responsibilities. Use this to manufacture under a loan licence. It has regulatory implications; have it reviewed by a lawyer and regulatory expert.

Third-Party Manufacturing Agreement

Drafts a third-party (contract) manufacturing agreement — a clause-by-clause draft covering products and specs, quality-agreement reference, pricing and MOQ, IP and brand, materials, batch release and QC, liability and recall, confidentiality, and term and termination. Use this to get products made by a CMO. Pair it with a quality agreement and have it legally reviewed.

Distribution / Stockist Agreement

Drafts a distribution or stockist agreement — a clause-by-clause draft covering territory, margins, stock and returns, expiry handling, licences and compliance, payment and credit, and term and termination. Use this to appoint stockists and distributors. Have it reviewed by a lawyer.

NDA Builder

Drafts an NDA for a pharma company — a clause-by-clause draft covering definition of confidential information, permitted use, exclusions, term, return, no-reverse-engineering, remedies and governing law. Use this to protect formulations and know-how when sharing with partners. Have it reviewed by a lawyer.

Quality Agreement Builder

Drafts a quality agreement structure between a pharma company and a manufacturer or supplier — a responsibilities matrix (QC, release, deviations, changes, complaints, recall, audits), specifications, documentation and communication. Use this to define quality roles with partners. A quality agreement is a GMP expectation; have QA and legal review. Pair it with the Third-Party Manufacturing Agreement.

Testing / Service Agreement

Drafts a testing or service agreement — a clause-by-clause draft covering scope of services, standards and methods, turnaround, confidentiality, data integrity, liability and term. Use this to engage labs and service providers (e.g. a third-party testing lab or CRO). Have it reviewed by a lawyer.

Pharma Compliance Calendar

Builds a compliance calendar for a pharma business — each obligation (licence renewals, returns, stability and re-test, pollution, factory, GST) with the authority, frequency and typical due date — and the penalty-heavy items flagged. Use this to never miss a regulatory obligation. Confirm exact obligations and dates for your unit. To identify all licences use the Pharma Licence Finder.

Pharmacovigilance Setup Guide

Explains pharmacovigilance setup for a pharma company — adverse event collection, assessment and reporting to PvPI/CDSCO, PSUR where applicable — with the setup (responsible person, SOPs, training) and records. Use this to monitor and report adverse events per PvPI and CDSCO requirements.

Pharma Licence Finder

Identifies the licences a pharma business needs based on its activity — drug manufacturing, wholesale/retail drug, product permissions, factory, pollution, fire, GST, FSSAI (nutraceutical) and cosmetic — with the authority, when each is needed and a priority order. Use this to know every licence your business needs. Requirements vary by activity and state; confirm with your state FDA.

This is AI-assisted guidance. Verify with a qualified professional before any binding decision. Fees, authorities and processes vary by state and change over time — confirm with your state authority.