AI Governance SOP Outline

Professional GMP / Pharma QA Tool for AIforQA.org

Document Type	SOP Outline / Template
Intended Users	QA Managers; Compliance Managers; Validation Leaders; CSV Specialists; IT Quality Teams; Regulatory Affairs; Senior Quality Leadership
Primary Use	Create or adapt an internal SOP governing the use of AI tools in GMP/GxP, QA, compliance, validation, documentation, and business processes.
Document Status	Template - adapt to site procedures, quality system requirements, validation approach, and applicable regulations.

1. Short Description

This SOP outline provides a practical structure for creating an internal company procedure governing the approved, controlled, and compliant use of artificial intelligence tools in pharmaceutical quality systems. It is intended to help organizations define approved AI uses, prohibited uses, data entry restrictions, human review requirements, validation expectations, documentation requirements, and governance controls.

2. Intended Use

Use this SOP outline before approving AI tools, before employees use ChatGPT/Copilot or similar tools for QA work, before implementing AI-enabled GxP systems, and before using AI to support document review, deviation support, training, regulatory intelligence, data analytics, or quality system workflows.

- ☐ Before approving any AI tool for business or GMP-supporting use.
- ☐ Before employees use ChatGPT, Copilot, NotebookLM, or similar tools for QA, validation, compliance, or documentation work.
- ☐ Before implementing AI-enabled GxP systems or AI functions in QMS, LMS, LIMS, MES, ERP, EDMS, CMMS, or analytics platforms.
- ☐ Before using AI for SOP review, deviation/CAPA support, training content, regulatory summaries, batch review support, risk assessments, or quality analytics.

3. Scope

The SOP developed from this outline should define the governance requirements for approved AI tools and AI-enabled systems used in GMP/GxP, QA, validation, compliance, documentation, regulatory, training, IT quality, and business processes.

Included	Approved AI tools; AI-enabled software; AI-generated or AI-assisted content; GMP and non-GMP AI activities; validation expectations; human review; AI use logs; AI supplier controls; AI change control; training; record retention; periodic review.
Excluded	Personal use unrelated to company work; non-company AI experimentation not connected to company records or decisions; tools that do not use AI or machine learning functionality; AI use prohibited by company policy or law.

4. SOP Outline

The following numbered sections may be adapted into a formal internal SOP. Each section includes suggested content and minimum expectations.

1. Purpose

State that the SOP establishes requirements for controlled use of AI tools in GMP/GxP, QA, compliance, validation, documentation, training, regulatory, and business processes. Emphasize patient safety, product quality, data integrity, confidentiality, and human accountability.

2. Scope

Define applicable AI tools, business processes, departments, users, systems, records, and environments. Clarify which AI uses are non-GMP, GMP-supporting, GMP-impacting, or prohibited.

3. Definitions

Include definitions for AI tool, AI-enabled system, generative AI, machine learning model, intended use, GxP impact, GMP record, human review, validation, data integrity, audit trail, supplier qualification, confidential information, and AI output.

4. Responsibilities

Define responsibilities for QA, Compliance, IT, CSV/Validation, Regulatory Affairs, System Owners, Business Process Owners, End Users, Vendor Management, and Senior Quality Leadership.

5. AI Use Classification

Define AI use categories and required controls for each category. Include non-GMP administrative use, GMP-supporting use, GMP-impacting use, and AI automated decision-making.

6. Approved AI Uses

List permitted AI activities, such as brainstorming, drafting non-final content, summarizing publicly available regulations, controlled document review support, similarity search, training draft support, regulatory monitoring, analytics support, and validated decision-support use where approved.

7. Prohibited AI Uses

Define uses that are not permitted, including entering restricted data into unapproved public AI tools, allowing AI to make batch disposition decisions, using unverified AI output in official GMP records, or using unvalidated AI for GMP decisions.

8. Data Entry Restrictions

Define what data may and may not be entered into AI tools. Address confidential information, proprietary formulas, batch records, patient data, personal data, regulatory submissions, supplier proprietary information, and controlled GMP records.

9. Human Review Requirements

Require qualified human review, verification, and approval before AI output is used in GMP, compliance, validation, regulatory, training, or quality system contexts. State that accountability cannot be delegated to AI.

10. AI-Generated Content Review

Define requirements for reviewing AI-generated or AI-assisted content before use. Include source verification, accuracy review, regulatory alignment, SOP alignment, hallucination check, data integrity review, and final approval.

11. GxP Impact Assessment

Require assessment of intended use, supported process, data inputs, outputs, GMP record impact, decision impact, patient/product risk, and required level of control before AI use.

12. Validation Requirements

Define when validation is required based on intended use and GxP impact. Include URS, risk assessment, configuration, testing, model behavior, data integrity, audit trail, access control, Part 11/Annex 11, and periodic review expectations.

13. Change Control Requirements

Define change control triggers for new AI tools, AI model updates, software upgrades, prompt/workflow changes, output-use changes, data source changes, interface changes, vendor changes, hosting changes, and retirement.

14. Vendor/Supplier Qualification

Define supplier assessment expectations for AI vendors, including GMP understanding, documentation, validation support, cybersecurity, data handling, model updates, auditability, support, and contract requirements.

15. Cybersecurity and Data Protection

Define controls for access, encryption, authentication, data retention, cloud hosting, backups, incident response, personal data, confidential information, and data loss prevention.

16. Documentation and Record Retention

Define required records, including AI use logs, risk assessments, validation records, change controls, supplier documentation, training records, review checklists, approvals, and periodic reviews.

17. Training Requirements

Require training for approved AI users. Training should address permitted use, prohibited use, data restrictions, human review, hallucination risk, confidentiality, data integrity, and escalation.

18. Periodic Review

Require periodic review of approved AI tools, use logs, incidents, deviations, model changes, performance, user feedback, supplier status, and continued suitability.

19. Deviation Handling

Define when AI-related issues require deviation, CAPA, incident, or security event handling. Include incorrect AI outputs used in GMP records, unauthorized data entry, model failures, missed outputs, or vendor/security incidents.

20. Audit and Inspection Readiness

Define how the company will demonstrate governance during audits or inspections, including approved tool list, intended use, validation status, change controls, use logs, training, supplier records, and human review evidence.

21. References

List applicable internal procedures and external references, such as 21 CFR Part 11, EU GMP Annex 11, ICH Q9, ICH Q10, data integrity guidance, computerized system validation procedures, and company quality policies.

22. Attachments / Forms

List required attachments and forms, such as AI Tool Risk Assessment Checklist, AI Use Log, AI-Generated Content Review Checklist, AI Change Control Impact Assessment, AI Supplier Questionnaire, and Approved AI Tool List.

5. Responsibilities Table

Function / Role	Responsibilities
QA	Own or approve AI governance SOP; assess GMP impact; approve GMP-supporting and GMP-impacting AI uses; review deviations/CAPAs; ensure inspection readiness.
IT	Assess infrastructure, access, cybersecurity, hosting, integrations, backups, user management, and technical controls.
CSV / Validation	Determine validation strategy; assess Part 11/Annex 11 impact; create/execute validation deliverables; evaluate model updates and periodic review.
Business Process Owner	Define business process, intended use, operational needs, expected outputs, user roles, and process risks.
System Owner	Maintain system inventory, validation status, procedures, user access, periodic review, change control, and supplier relationship.
End Users	Use only approved AI tools for approved purposes; follow data restrictions; verify AI output; document use where required; escalate issues.
Vendor Management	Support supplier qualification, contracts, quality agreements, vendor documentation, audit coordination, and vendor change notifications.
Regulatory Affairs	Assess regulatory impact, filing commitments, regulatory intelligence, external communication risks, and jurisdiction-specific requirements.

6. AI Use Classification Table

Classification	Description	Minimum Control Expectation
Uncontrolled personal use	Personal experimentation or non-company use outside approved company processes.	Not permitted for company confidential, GMP, GxP, or business-sensitive information. No company data entry.
Approved non-GMP administrative use	Low-risk administrative support such as meeting agenda drafts, generic brainstorming, formatting, or non-confidential business writing.	Use approved tools only. No GMP record generation. Human review required before business use.
GMP-supporting use	AI supports drafting, summarizing, searching, or reviewing information that may support a GMP process but does not make final decisions.	Risk assessment, human review, source verification, documented use where required, and applicable approval.
GMP-impacting use	AI output influences GMP records, investigations, validation, training, quality decisions, QMS workflows, or compliance conclusions.	Formal risk assessment, validation assessment, change control, approved procedures, audit trail, human approval, and periodic review.
AI automated decision-making	AI executes or recommends decisions without meaningful human review, such as batch release, deviation closure, CAPA approval, or disposition decisions.	Generally prohibited unless specifically justified, validated, approved by Quality, controlled by procedure, and allowed by company policy and applicable regulations.

7. Prohibited Use Examples

- Entering confidential batch data, product formulas, process parameters, customer complaints, patient information, personal data, supplier proprietary information, or regulatory submission content into unapproved public AI tools.
- Using AI output directly in GMP records without qualified human review, source verification, and required approval.
- Allowing AI to make or approve batch disposition, product release, deviation closure, CAPA approval, regulatory reporting, or validation acceptance decisions.
- Using unvalidated AI tools to perform GMP decisions, generate official quality conclusions, modify regulated records, or replace required Quality Unit review.
- Using AI to bypass company procedures, review steps, segregation of duties, electronic signature requirements, change control, or validation requirements.
- Using AI-generated regulatory interpretation as final without Regulatory Affairs or QA verification against authoritative sources.

8. Required Attachments / Suggested Forms

Attachment	Form / Record	Purpose
Attachment A	AI Tool Risk Assessment Checklist	Assess whether an AI tool can be used in a GMP/GxP environment and what level of control is required.
Attachment B	AI Use Log	Document AI usage, classification, data entered, output used, human reviewer, decision-maker, and follow-up.
Attachment C	AI-Generated Content Review Checklist	Verify accuracy, source support, regulatory alignment, SOP alignment, hallucination risk, and approval readiness.
Attachment D	AI Change Control Impact Assessment	Assess impact for new AI implementations, model updates, upgrades, integrations, workflow changes, hosting changes, and retirement.
Attachment E	AI Supplier Questionnaire	Evaluate AI vendor controls, quality documentation, cybersecurity, data handling, model governance, change notifications, and validation support.
Attachment F	Approved AI Tool List	Maintain authorized AI tools, approved uses, owners, validation status, restrictions, training requirements, and periodic review dates.

9. SOP Drafting Notes

- Define whether AI governance applies globally, site-wide, departmentally, or by system/process.
- Make the approved AI tool list controlled and easy for employees to find.
- Require clear distinction between non-GMP use, GMP-supporting use, and GMP-impacting use.
- Require source verification before AI-generated content is used in regulated or compliance-related documents.
- Define when AI use must be logged and when QA approval is required.
- Define escalation requirements for incorrect AI outputs, unauthorized AI use, data leakage, and potential GMP impact.
- Align the SOP with existing procedures for document control, validation, change control, training, cybersecurity, data privacy, vendor qualification, deviation, and CAPA.

10. SOP Outline Approval / Review Table

Role	Name	Department	Signature	Date	Comments
Prepared by					
Reviewed by					
Approved by					

11. Disclaimer

This tool is intended as a practical quality assurance aid and does not replace company procedures, regulatory requirements, or formal validation/compliance review.

12. Website Integration Block

SEO Title	AI Governance SOP Outline for GMP and Pharma QA Teams
Meta Description	Download an AI Governance SOP outline for GMP, QA, validation, compliance, IT quality, and pharmaceutical AI use controls.
Recommended URL Slug	/tools/ai-governance-sop-outline
Recommended Tags	AI governance; GMP; pharma QA; GxP; compliance; CSV; validation; SOP template; data integrity; AI tools
Short Website Excerpt	A practical SOP outline pharmaceutical companies can adapt to govern AI use in GMP/GxP, QA, compliance, validation, documentation, and business processes.
Related AIforQA.org Article Ideas	What Happens When AI Makes a GMP Mistake?; AI for GMP Document Review and Approval Workflows; AI for Change Control Impact Assessments; AI Validation Readiness in GMP Environments; AI and Pharmaceutical Knowledge Management
Suggested Internal Links	/tools/ai-tool-gmp-risk-assessment-checklist; /tools/chatgpt-ai-use-log-qa-teams; /tools/ai-generated-content-review-checklist; /tools/ai-validation-readiness-assessment; /tools/ai-change-control-impact-assessment-template