

# ChatGPT / AI Use Log for QA Teams

## GMP / GxP AI Usage Documentation Template

### Short Description

This log helps pharmaceutical QA teams document when AI tools are used, support traceability, and distinguish GMP, GMP-supporting, non-GMP, and prohibited AI activities. It is designed for QA, CSV, validation, compliance, document control, and IT Quality teams that need a practical record of AI use in quality workflows.

Field	Entry
Site / Company	
Department / Function	
Log Period	From: _____ To: _____
AI Tools Covered	ChatGPT, Copilot, NotebookLM, internal AI tools, vendor AI platforms, or other: _____
Procedure / Policy Reference	
Document No. / Version	

## 1. Intended Use

- when AI is used to draft, revise, review, summarize, or brainstorm QA documents;
- when AI is used to summarize regulations, guidance, procedures, or inspection expectations;
- when AI is used to support deviation, CAPA, change control, complaint, APR/PQR, validation, CSV, or risk assessment drafting;
- when AI is used to create, review, or simplify training content;
- when AI is used for non-GMP brainstorming or administrative work in a QA context;
- when AI output may influence quality decisions, GMP documentation, compliance conclusions, or regulated records.

## 2. Scope

Included Uses	Excluded / Not Covered Uses
AI-assisted drafting, review, summarization, comparison, brainstorming, data organization, trend explanation, training support, document review, and quality-system administrative support.	Formal validation protocols and executed validation evidence. This log does not replace validation deliverables, approved SOPs, change controls, deviation records, CAPA records, or formal regulatory assessments.
Use of public AI tools, enterprise AI tools, embedded AI features in QMS/LMS/LIMS/MES/ERP/document systems, and internal AI assistants where AI output may be used by QA or related functions.	Unapproved use of AI with restricted, confidential, patient, batch, formula, trade secret, or official GMP record data. These uses require company approval before entry into an AI tool.

## 3. User Instructions

1. Assign a unique Log ID for each AI-assisted activity.
2. Record the date, user, department, and AI tool used.
3. Describe the activity or purpose in practical terms.
4. Classify the use as Administrative / non-GMP, GMP-supporting but not decision-making, GMP-impacting, or Prohibited / not approved.

5. Identify the system, process, document, or quality workflow supported.
6. Describe the data entered into the AI tool. Do not paste sensitive data into this log; summarize the type of data.
7. Confirm whether confidential or GMP data were entered into the AI tool.
8. Describe the AI output generated and whether it was used.
9. Identify the human reviewer and final decision maker.
10. Record required follow-up, such as human verification, SOP review, QA approval, change control, validation assessment, or correction of AI output.
11. Complete comments/justification so the use can be reconstructed later.
12. Escalate any prohibited, unapproved, or potentially GMP-impacting use to QA management or the designated AI governance owner.

## 4. Key Definitions

Term	Definition
AI-assisted activity	Any activity where an AI tool is used to draft, summarize, analyze, organize, compare, classify, search, or generate content that may support work performed by QA or related functions.
GMP use	Use of AI in a way that directly supports or influences a GMP/GxP process, regulated record, compliance conclusion, investigation, validation activity, quality decision, batch-related decision, or approved quality system workflow.
Non-GMP use	Administrative, educational, brainstorming, formatting, or general productivity use that does not influence GMP records, quality decisions, compliance conclusions, or regulated processes.
AI output	Any text, summary, recommendation, table, code, analysis, classification, prompt response, or generated content produced by an AI tool.
Human review	Documented review by a qualified person to verify AI output against approved procedures, source records, regulatory requirements, and applicable quality standards before use.
Final decision maker	The authorized individual or function that makes the final GMP, quality, compliance, validation, training, or administrative decision after considering AI output and human review.
Confidential information	Company information not approved for external disclosure, including proprietary processes, formulas, batch data, product data, supplier information, investigations, regulatory strategy, patient data, employee data, or trade secrets.
Quality record	A controlled GMP/GxP record used as evidence of a regulated activity, quality decision, compliance conclusion, review, approval, investigation, validation, training, or product/process control.

## 5. AI Use Log Table

Complete one row for each AI-assisted activity. Use additional rows as needed. For long descriptions, attach supporting records or continuation pages.

Log ID	Date	User / Department	AI Tool Used	Activity / Purpose	GMP or Non-GMP Classification	System / Process Supported	Data Entered Into AI	Confidential or GMP Data Entered? Yes/No	AI Output Generated	Output Used? Yes/No	Human Reviewer	Final Decision Made By	Required Follow-Up	Comments

## 6. Classification Guide

Classification	Criteria	Typical Risk Level	Required Control
Administrative / non-GMP	AI is used for general brainstorming, wording improvements, meeting notes, non-regulated planning, formatting, or educational understanding. Output does not enter GMP records and does not influence quality decisions.	Low	Human review recommended; do not include confidential or GMP data unless approved.
GMP-supporting but not decision-making	AI supports drafting, summarizing, searching, or organizing information for a GMP-related workflow, but a qualified human verifies all output and final GMP decisions are made outside the AI tool.	Medium	Human review required. Source verification required. Retain log entry and supporting evidence as applicable.
GMP-impacting	AI output may influence a regulated record, investigation, CAPA, deviation, validation activity, risk assessment, training requirement, QMS decision, batch-related decision, or compliance conclusion.	High	Formal risk assessment, QA approval, validation/CSV assessment, change control, and documented human review may be required before use.
Prohibited or not approved	AI is used with patient data, unapproved confidential data, batch records, proprietary formulas, official GMP records, restricted regulatory strategy, or AI output is copied into official records without verification/approval.	Not permitted	Stop use. Notify QA management, Compliance, IT Quality, or AI governance owner. Assess deviation or security escalation if required.

## 7. Data Entry Restrictions

Restriction	Requirement
No confidential data unless approved	Do not enter company-confidential or proprietary information into public or unapproved AI tools.
No batch records unless approved	Do not enter batch production/control records, lot numbers, raw batch data, or release-related records unless the AI tool and use case are formally approved.
No patient data	Do not enter patient-identifiable data, adverse event personal data, protected health information, or medical privacy information.
No proprietary formulas	Do not enter formulas, recipes, process secrets, technical transfer packages, or trade secrets unless approved and controlled.
No uncontrolled GMP records	Do not use uncontrolled copies of GMP records as source material for AI-generated conclusions.
No unverified AI output in official records	Do not copy AI output into official GMP records unless verified, edited as needed, and approved by a qualified human according to procedure.

## 8. Human Review Requirements

### Required Principle

AI output must be reviewed, verified, and approved by a qualified human before use in GMP or compliance contexts. AI may assist with drafting, summarizing, organizing, or suggesting content, but it must not independently make quality, compliance, validation, regulatory, or batch-related decisions.

Use Type	Human Review Expectation
Non-GMP administrative use	User reviews for accuracy and appropriateness before use.
GMP-supporting use	Qualified human verifies output against approved procedures, source records, and applicable requirements.

Use Type	Human Review Expectation
GMP-impacting use	QA/SME review required. Determine whether validation, change control, deviation, CAPA, or formal approval is required.
Uncertain classification	Escalate to QA management, Compliance, IT Quality, CSV, or AI governance owner before using the output.

## 9. Monthly QA Management Review

Monthly Review Item	Response / Notes
Review Period	From: _____ To: _____
Total Number of AI Uses Logged	
Types of Activities Observed	<input type="checkbox"/> Administrative / non-GMP <input type="checkbox"/> GMP-supporting <input type="checkbox"/> GMP-impacting <input type="checkbox"/> Prohibited / not approved
Deviations From Approved Use	<input type="checkbox"/> None identified <input type="checkbox"/> Yes - describe below
Repeated Issues or Trends	
Corrective Actions Required	<input type="checkbox"/> No <input type="checkbox"/> Yes - describe below
Items Escalated to QA / Compliance / IT Quality / CSV	
Reviewer Name / Title	
Reviewer Signature / Date	

## 10. Approval / Review Table

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

## 11. Required Documentation

- Completed AI Use Log entries
- Monthly QA management review records
- Associated AI risk assessment, if required
- Validation/CSV assessment, if applicable
- Vendor or supplier documentation, if applicable
- Change control record, if applicable
- Training record, if applicable
- Human review and approval evidence
- Deviation, CAPA, or security escalation record, if required

## 12. Disclaimer

### Disclaimer

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

## 13. Website Integration Block

Item	Recommendation
SEO title	ChatGPT / AI Use Log for QA Teams   GMP AI Documentation Template
Meta description	Download a GMP-ready AI use log for QA teams to document ChatGPT and AI tool usage, review, and controls.
Recommended URL slug	/tools/chatgpt-ai-use-log-qa-teams
Recommended tags	AI in QA; GMP tools; ChatGPT; quality systems; compliance; validation; CSV; data integrity
Short website excerpt	A practical log template for pharmaceutical QA teams to document AI use, classify GMP vs non-GMP activities, and support human review traceability.
Related AlforQA.org article ideas	AI Tool GMP Risk Assessment Checklist; What Happens When AI Makes a GMP Mistake?; AI for GMP Document Review and Approval Workflows; AI and GMP Knowledge Management; AI for Pharmaceutical Risk Management Under ICH Q9
Suggested internal links	/tools/ai-tool-gmp-risk-assessment-checklist; /articles/ai-gmp-document-review; /articles/ai-gmp-knowledge-management; /articles/ai-risk-management-ich-q9; /articles/ai-gmp-mistake