

AI Prompt Review and Approval Form

Controlled Prompt Governance Template for GMP / Pharma QA Use

1. Short Description

This form helps QA, Compliance, Validation, Documentation, Training, and IT Quality teams review, approve, version-control, and govern important prompts used for repeatable AI-assisted QA or compliance activities. It is intended to support traceability, consistency, human review, and control over prompts that may influence GMP-supporting workflows.

2. Intended Use

- SOP summaries or procedure explainers
- Deviation drafting support or investigation outline assistance
- CAPA brainstorming or effectiveness-check support
- Training content generation, quiz drafting, or competency material support
- Regulatory summary support or guidance comparison
- Document review assistance, consistency checks, or cross-reference review
- Audit preparation, inspection-readiness summaries, or response drafting
- Recurring quality reports, trend summaries, or management-review support

3. Scope

Category	Description
Included	Repeatable prompts used in approved AI tools for QA, compliance, validation, training, documentation, regulatory, or business-support workflows.
Included	Prompts that produce outputs used to support drafting, review, summarization, analysis, classification, or quality-system preparation activities.
Excluded	One-time personal experimentation, informal non-business prompts, or AI use prohibited by company policy.
Excluded	Prompts that would allow AI to make autonomous GMP decisions, batch disposition decisions, final regulatory interpretations, or unreviewed quality conclusions.

4. User Instructions

1. Assign a unique Prompt ID and complete all prompt information fields.
2. Paste the full prompt text exactly as intended for use, including placeholders and required variables.
3. Define the expected output type, format, limitations, source expectations, and human review requirements.
4. Identify prohibited inputs and confirm whether any confidential, proprietary, personal, or GMP data are restricted.
5. Complete the prompt risk assessment table and define required controls.
6. Route the form for review and approval according to company procedures.
7. Do not use the prompt in repeatable GMP-supporting workflows until approval is complete.
8. Reassess and reapprove the prompt after meaningful changes to prompt wording, AI tool/platform, intended use, data inputs, output use, or related procedures.

5. Key Definitions

Term	Definition
AI prompt	Instructions, questions, context, examples, variables, or constraints entered into an AI tool to generate a response.
Approved prompt	A prompt reviewed and approved for defined use under company governance controls.
Prompt version	The controlled version identifier assigned to a prompt after approval or revision.
Expected output	The defined type, structure, limitations, and review requirements of

	the AI-generated response.
Prohibited input	Data or information that must not be entered into the AI tool, including restricted GMP, confidential, personal, or proprietary information unless specifically approved.
Prompt owner	The individual or function responsible for maintaining the prompt, controlling revisions, and ensuring periodic review.
Human review	Review by a qualified person to verify accuracy, completeness, context, compliance alignment, and suitability before use.
Controlled prompt	A prompt managed under defined governance, approval, version control, and change control expectations.

6. Prompt Information

Prompt ID		Prompt Title	
Prompt Owner		Department	
AI Tool / Platform		Prompt Version	
Effective Date		Frequency of Use	
Intended Use		GxP Classification	
Related SOP / Process		Related System / Workflow	

7. Approved Prompt Text

<p>Full Approved Prompt Text Paste the full approved prompt exactly as it should be used. Include all required instructions, constraints, formatting requirements, source expectations, and output limitations.</p> <p>[Enter full prompt text here]</p>
<p>Required Variables / Placeholders List all placeholders that users must replace before running the prompt, such as [PRODUCT], [SOP NUMBER], [DOCUMENT TITLE], [REGULATION], [AUDIENCE], [OUTPUT FORMAT], or [DATE RANGE].</p> <p>[Enter variables/placeholders here]</p>
<p>Instructions for Replacing Placeholders Explain how users must replace placeholders and what information is prohibited or restricted.</p> <p>[Enter instructions here]</p>

8. Expected Output

Expected Output Type	<input type="checkbox"/> Summary <input type="checkbox"/> Draft text <input type="checkbox"/> Checklist <input type="checkbox"/> Table <input type="checkbox"/> Review comments <input type="checkbox"/> Training content <input type="checkbox"/> Other: _____
Acceptable Format	
Required Sections	
Required Limitations	
Expected Sources / References	
Human Review Requirements	

9. Prohibited Inputs

Prohibited Input Category	Comments / Restrictions
<input type="checkbox"/> Confidential batch data	Comments:
<input type="checkbox"/> Patient data / PHI / personally identifiable information	Comments:
<input type="checkbox"/> Proprietary formulas, process parameters, or trade secrets	Comments:
<input type="checkbox"/> Unreleased regulatory data or agency correspondence	Comments:
<input type="checkbox"/> Employee personal data	Comments:
<input type="checkbox"/> Uncontrolled GMP records, draft batch records, or raw data exports	Comments:
<input type="checkbox"/> Supplier confidential data or quality agreements	Comments:
<input type="checkbox"/> Other restricted information: _____	Comments:

10. Prompt Risk Assessment

Risk Area	Assessment Question	Yes	No	N/A	Required Control	Comments
GMP Impact	Could the prompt output influence a GMP, GxP, quality, validation, compliance, training, or regulatory activity?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Define GxP classification and required human review.	
Data Integrity	Could the prompt or output affect a quality record, data interpretation, traceability, or ALCOA+ expectation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Require source verification and retain review evidence where applicable.	
Hallucination Risk	Could the AI generate inaccurate facts, fabricated references, incorrect regulations, or unsupported conclusions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Require independent source verification before use.	
Confidentiality	Could users enter confidential, proprietary, personal, supplier, or restricted information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Define prohibited inputs and approved data-handling controls.	
Repeatability	Must the prompt generate consistent output across repeated use or users?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Control prompt wording, version, variables, and output format.	
Output Verification	Does the output require qualified human verification before use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Define reviewer role, review criteria, and approval pathway.	
Validation Impact	Could the prompt be part of a validated system, repeatable GMP workflow, or automated decision-support process?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Assess validation/CSV requirements before implementation.	
Change Control Impact	Would changes to the prompt, tool, model, data inputs, output use, or workflow require reassessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Define change control triggers and revision history requirements.	

11. Approval Decision

- Approved
- Approved with restrictions
- Not approved
- Requires further validation/compliance review

Restrictions / Conditions of Use Document any approved restrictions, required review steps, approved users, allowed systems, prohibited data, or required evidence. [Enter restrictions or conditions here]
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12. Revision History

Version	Description of Change	Reason for Change	Reviewed By	Approved By	Date

13. Approval Table

Role	Name	Department	Signature	Date
Prepared by				
Reviewed by				
Approved by				

14. 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.

15. Website Integration Block

Website Field	Recommendation
SEO Title	AI Prompt Review and Approval Form for GMP and Pharma QA Teams
Meta Description	Download an AI prompt review and approval form for GMP QA teams to control prompts, versions, risk, and human review.
Recommended URL Slug	/tools/ai-prompt-review-approval-form
Recommended Tags	AI governance, GMP, QA, prompt control, AI validation, compliance, document control, CSV
Short Website Excerpt	A practical GMP/Pharma QA form for reviewing, approving, version-controlling, and governing AI prompts used in repeatable quality workflows.
Related Article Ideas	AI Governance SOP Outline; AI for GMP Document Review; What Happens When AI Makes a GMP Mistake?; AI for Change Control Impact Assessments
Suggested Internal Links	/tools/ai-tool-gmp-risk-assessment-checklist; /tools/ai-generated-content-review-checklist; /tools/ai-use-log-for-qa-teams; /articles/ai-governance-gmp