# AI-Generated Content Review Checklist

*A practical GMP/Pharma QA checklist for reviewing AI-generated or AI-assisted content before use in quality, compliance, validation, training, regulatory, or business documents.*

## Short Description

This checklist helps QA, Compliance, Validation, Documentation, Training, and Regulatory teams verify AI-generated content for accuracy, compliance alignment, traceability, data integrity, confidentiality, and suitability before use. It is designed to support documented human review and distinguish acceptable drafting support from content that is not suitable for GMP use.

## Purpose

Use this checklist before AI-generated or AI-assisted content is copied, adapted, summarized, referenced, or relied upon in any quality, GMP, compliance, validation, training, regulatory, audit, or business document.

## Intended Use

Complete this checklist when reviewing AI-generated or AI-assisted content, including but not limited to:

- SOP drafts or procedure sections
- Deviation summaries or investigation draft language
- CAPA drafts, effectiveness check summaries, or action-plan language
- Training content, quizzes, learning summaries, or competency materials
- Regulatory summaries, guidance interpretations, or inspection-readiness materials
- Validation summaries, protocol/report draft sections, or CSV support text
- Risk assessments, FMEA drafts, impact assessments, or quality decision-support text
- Audit responses, quality reports, management review inputs, or APR/PQR summaries

## Scope

| Scope Area | Description |
|---|---|
| Included | AI-generated or AI-assisted text, tables, summaries, checklists, comments, narratives, training content, regulatory summaries, risk assessments, validation summaries, and review notes intended for quality or business use. |
| Excluded | Raw AI prompts not retained as records unless required by company procedure; informal personal use unrelated to company activities; AI software validation activities covered by a separate system validation procedure; final GMP approval decisions, which must be made by authorized personnel. |
| Important Boundary | This checklist reviews the content generated by AI. It does not by itself approve the AI tool, validate the system, or authorize entry of confidential/GMP data into AI systems. |

## User Instructions

1. Identify the AI-generated or AI-assisted content to be reviewed and the document or process where it may be used.
2. Determine whether the content is intended for GMP, GxP, compliance, validation, training, regulatory, audit, or business use.
3. Verify all factual claims, regulations, guidance references, internal SOP references, numerical values, definitions, and technical conclusions against approved sources.

4. Complete each checklist question by marking Yes, No, or N/A. Use N/A only when the question is clearly not applicable and provide justification when needed.

5. Document required actions for any No response, unresolved concern, missing source, unclear statement, or unsupported conclusion.

6. Retain the original AI output, revised final version, reviewer comments, and source verification evidence according to company procedures.

7. Do not use AI content in GMP records or compliance documents until qualified human review and required approval are complete.

## Key Definitions

| Term | Definition |
|---|---|
| AI-generated content | Content created primarily by an artificial intelligence tool in response to a prompt or instruction. |
| AI-assisted content | Content drafted, edited, summarized, translated, analyzed, or organized with support from an AI tool, even if later revised by a human. |
| Hallucination | An inaccurate, fabricated, unsupported, or misleading AI output that may appear confident or credible but is not verified by reliable sources. |
| Source verification | Documented confirmation that AI content was checked against approved regulations, guidance, internal procedures, controlled records, or qualified references. |
| GMP record | A controlled record required to demonstrate compliance with GMP requirements, company procedures, product quality decisions, or regulated activities. |
| Human review | Review by a qualified person who verifies the AI output, challenges unsupported content, and determines whether the content is suitable for use. |
| Final approval | Formal approval by the authorized role or function responsible for the final document, record, decision, or communication. |
| Traceability | The ability to reconstruct the origin, source verification, edits, reviewer decisions, and approval history of the AI-generated or AI-assisted content. |

## Main Review Checklist

Mark Yes, No, or N/A for each question. Any No response must include a required action before the content is used. Use the Comments / Evidence column to reference verified sources, SOPs, reviewer rationale, or required follow-up.

| Review Area | Review Question | Yes | No | N/A | Required Action | Comments / Evidence |
|---|---|---|---|---|---|---|
| Accuracy | Are factual statements, technical claims, definitions, and calculations accurate when checked against approved sources? | ☐ | ☐ | ☐ | Correct inaccurate content or reject output. | |
| Accuracy | Are dates, names, product/process references, quantities, limits, and terminology correct? | ☐ | ☐ | ☐ | Verify and correct all values before use. | |
| Completeness | Does the content include all required context needed to avoid misleading interpretation? | ☐ | ☐ | ☐ | Add missing context or restrict use. | |
| Completeness | Does the content avoid omitting critical exceptions, limitations, assumptions, or procedural conditions? | ☐ | ☐ | ☐ | Document assumptions and limitations. | |
| Regulatory alignment | Are regulatory statements aligned with current applicable FDA, EMA, ICH, PIC/S, WHO, or other relevant expectations? | ☐ | ☐ | ☐ | Verify against official source and revise. | |
| Regulatory alignment | Does the content avoid presenting guidance, interpretation, or opinion as binding regulation unless verified? | ☐ | ☐ | ☐ | Clarify wording and add source context. | |
| Company procedure alignment | Is the content consistent with current approved internal SOPs, policies, forms, templates, and quality standards? | ☐ | ☐ | ☐ | Revise to match approved company procedure. | |
| Company procedure alignment | Does the content avoid creating new unofficial instructions that conflict with controlled procedures? | ☐ | ☐ | ☐ | Remove or route through document change control. | |
| Source verification | Are all important claims traceable to reliable external or internal sources? | ☐ | ☐ | ☐ | Add source evidence or remove unsupported claim. | |
| Source verification | Are source citations, document numbers, titles, revisions, and sections accurate? | ☐ | ☐ | ☐ | Correct citation/source information. | |

## Main Review Checklist - Continued

| Review Area | Review Question | Yes | No | N/A | Required Action | Comments / Evidence |
|---|---|---|---|---|---|---|
| Hallucinated references | Were all references checked to confirm they exist and support the statement made? | ☐ | ☐ | ☐ | Remove fabricated or unsupported references. | |
| Hallucinated references | Does the AI output avoid invented policies, false requirements, fake citations, or non-existent documents? | ☐ | ☐ | ☐ | Reject or rewrite content with verified sources. | |
| Missing context | Does the content identify intended use, scope, exclusions, and limitations where relevant? | ☐ | ☐ | ☐ | Add intended use/scope/limitations. | |
| Missing context | Is product-, site-, system-, or process-specific context verified before use? | ☐ | ☐ | ☐ | Add verified site/product/process context. | |
| Data integrity | Does the content preserve original meaning without altering source data, results, or records? | ☐ | ☐ | ☐ | Investigate and correct altered meaning. | |
| Data integrity | Are AI-generated summaries clearly distinguished from original records or approved conclusions? | ☐ | ☐ | ☐ | Label as draft/summary and verify. | |
| ALCOA+ | Is the content attributable, legible, contemporaneous where applicable, original/source-traceable, accurate, complete, consistent, enduring, and available? | ☐ | ☐ | ☐ | Address ALCOA+ gap before use. | |
| 21 CFR Part 11 | If the content will become an electronic GMP record, are applicable electronic record/signature controls considered? | ☐ | ☐ | ☐ | Consult CSV/QA; assess Part 11 impact. | |
| 21 CFR Part 11 | Are AI outputs, edits, reviews, and approvals retained or controlled as required by procedure? | ☐ | ☐ | ☐ | Define retention and audit trail expectations. | |
| Confidentiality | Does the content avoid exposing confidential, proprietary, patient, batch, formula, supplier, or controlled GMP information inappropriately? | ☐ | ☐ | ☐ | Remove sensitive data; escalate if exposed. | |

## Main Review Checklist - Continued

| Review Area | Review Question | Yes | No | N/A | Required Action | Comments / Evidence |
|---|---|---|---|---|---|---|
| Confidentiality | Was the AI tool approved for the type of data entered and output generated? | ☐ | ☐ | ☐ | Stop use and perform tool/data-use assessment. | |
| Bias or unsupported conclusions | Does the content avoid unsupported conclusions, exaggerated certainty, or one-sided interpretations? | ☐ | ☐ | ☐ | Add evidence, uncertainty, or balanced rationale. | |
| Bias or unsupported conclusions | Are quality, compliance, validation, regulatory, or risk conclusions supported by qualified human judgment? | ☐ | ☐ | ☐ | Route to qualified reviewer/SME. | |
| Human review | Has a qualified human reviewer verified the AI output before use? | ☐ | ☐ | ☐ | Complete qualified review before use. | |
| Human review | Were reviewer edits, accepted/rejected AI suggestions, and final rationale documented where required? | ☐ | ☐ | ☐ | Document review history and rationale. | |
| Approval readiness | Is the content suitable for the intended document or record after review and edits? | ☐ | ☐ | ☐ | Revise, reject, or restrict to non-GMP use. | |
| Approval readiness | Has the content received all required approvals before implementation or official use? | ☐ | ☐ | ☐ | Obtain required approvals before use. | |

## Source Verification Section

| Verification Field | Entry |
|---|---|
| Sources checked | _____ |
| Regulations/guidance verified | _____ |
| Internal SOPs checked | _____ |
| Controlled records/templates checked | _____ |
| Reviewer initials | _____ |
| Date verified | _____ |

## AI Output Disposition

☐ Accepted as written
☐ Accepted with edits
☐ Requires major revision
☐ Rejected
☐ Not suitable for GMP use

## Required Documentation to Retain

- Original AI output or AI-generated draft, where required by procedure
- Revised final version used in the document or record
- Reviewer comments, edits, and documented rationale
- Source verification evidence, including external references and internal SOP/record checks
- Approval record, including required SME, QA, Compliance, Validation, Training, Regulatory, or Document Control approval

## Approval Table

| Role | Name | Department | Signature | Date |
|---|---|---|---|---|
| Prepared by | | | | |
| Reviewed by | | | | |
| Approved by | | | | |

## Disclaimer

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

## Website Integration Block

| Website Field | Recommended Content |
|---|---|
| SEO title | AI-Generated Content Review Checklist for GMP and Pharma QA Teams |
| Meta description | Review AI-generated GMP content for accuracy, compliance, traceability, and approval readiness before use. |
| Recommended URL slug | /tools/ai-generated-content-review-checklist |
| Recommended tags | AI in QA; GMP documentation; AI content review; compliance checklist; data integrity; pharmaceutical quality systems |
| Short website excerpt | Download a practical GMP checklist for reviewing AI-generated SOP drafts, deviation summaries, CAPA drafts, training content, regulatory |

| Website Field | Recommended Content |
|---|---|
| | summaries, validation summaries, and quality reports before use. |
| Related AIforQA.org article ideas | What Happens When AI Makes a GMP Mistake?; AI for GMP Document Review and Approval Workflows; AI-Assisted Root Cause Analysis; AI for Pharmaceutical Risk Management Under ICH Q9; AI Tool GMP Risk Assessment Checklist |
| Suggested internal links | /articles/what-happens-when-ai-makes-a-gmp-mistake; /articles/ai-gmp-document-review-approval-workflows; /articles/ai-assisted-root-cause-analysis; /tools/ai-tool-gmp-risk-assessment-checklist; /tools/chatgpt-ai-use-log-qa-teams |