AI Tool GMP Risk Assessment Checklist

A practical QA template for assessing AI tools before use in GMP/GxP environments

Document Owner	Version	Effective Date	Page
	1.0		
Site / Department	**AI Tool Name**	**AI Tool Vendor / Provider**	**Assessment ID**
Assessment Date	**Assessor**	**Business Process / Workflow**	**GMP/GxP System(s) Affected**

1. Short Description

This checklist helps Quality Assurance, Validation, CSV, Compliance, Regulatory Affairs, and IT Quality teams assess whether an AI tool can be used in a GMP/GxP process and what level of control is required before use. It is designed for practical pre-use assessment of AI tools such as ChatGPT, Microsoft Copilot, NotebookLM, document intelligence tools, AI-enabled QMS modules, AI search tools, AI analytics platforms, and other software that may support pharmaceutical quality activities.

2. Intended Use

- Before introducing ChatGPT, Copilot, NotebookLM, or other AI tools into QA, validation, CSV, compliance, regulatory, or IT Quality workflows.
- Before using AI to support GMP documentation, SOP drafting, deviation investigation support, CAPA analysis, change control impact assessments, APR/PQR summaries, training content, batch record review support, or regulatory intelligence activities.
- Before using AI to summarize, analyze, classify, compare, or generate quality records or regulated content.
- Before connecting AI software to QMS, LMS, ERP, LIMS, MES, CMMS, document management systems, calibration systems, complaint systems, regulatory systems, or validated data repositories.
- Before allowing AI outputs to influence GMP decisions, risk assessments, investigations, records, reports, workflows, or review activities.

3. Scope

Included in Scope	Excluded from Scope
AI tools used to support GMP/GxP activities, quality workflows, regulated records, or validated systems.	AI tools used only for personal productivity with no GMP/GxP data, no quality records, no regulated decision support, and no company confidential information.
AI tools used to search, summarize, compare, draft, classify, trend, analyze, or recommend content related to pharmaceutical quality systems.	General internet searches or public educational use where no proprietary, confidential, patient, product, batch, supplier, employee, or GMP data are entered.
AI tools integrated with or connected to QMS, DMS, LMS, LIMS, MES, ERP, CMMS, SCADA/historian, calibration, complaint, deviation, CAPA, or regulatory systems.	AI outputs used only as informal brainstorming and not copied into, attached to, or relied upon for GMP records or decisions.
AI tools that may create, modify, maintain, retrieve, archive, transmit, or influence electronic GMP records.	Non-GMP marketing, graphic design, or general writing tools where content is reviewed independently and does not affect GMP operations.

4. User Instructions

1. Identify the AI tool, vendor/provider, version if known, and the business process where it may be used.
2. Define the intended use clearly. Be specific about what users will enter, what the AI will generate, and what decisions may be influenced.
3. 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.

4. Assign or confirm the risk impact for each applicable question: Low, Medium, or High. Use the risk classification table in Section 9.

5. Document comments and justification. Include supporting evidence such as SOP references, vendor documentation, validation documents, data flow diagrams, or risk assessments.

6. If any High Risk item is identified, escalate to QA/Compliance/Validation/CSV before use.

7. Complete the final decision section. Do not use the AI tool in a GMP/GxP workflow until the required approval, validation, change control, training, and documentation are completed.

8. Retain the completed checklist and supporting documents according to company record retention procedures.

5. Key Definitions

Term	Definition
AI tool	Any software, platform, model, feature, or system that uses artificial intelligence, machine learning, natural language processing, generative AI, automated classification, predictive analytics, or algorithmic decision support to generate, analyze, summarize, classify, search, recommend, or predict information.
GxP impact	The potential for a tool, record, data, output, or decision to affect GMP, GLP, GCP, GDP, product quality, patient safety, data integrity, regulatory compliance, or the validated state of a system or process.
GMP record	Any record required by GMP regulations or company procedures to demonstrate manufacturing, testing, control, review, investigation, approval, release, distribution, training, validation, maintenance, calibration, or quality system activities.
Intended use	The formally defined purpose and boundaries for how the AI tool will be used, including input data, output type, users, workflow, affected systems, and decisions influenced.
Human review	Review by trained and authorized personnel who evaluate AI outputs against source data, procedures, scientific rationale, GMP expectations, and company requirements before use in any decision or record.
Validation	Documented evidence that a computerized system, software function, AI-enabled feature, workflow, or data process performs as intended and remains controlled for its approved intended use.
Data integrity	The degree to which data are complete, consistent, accurate, attributable, legible, contemporaneous, original, enduring, available, and protected from unauthorized or undocumented alteration.
Supplier qualification	The documented evaluation and approval of a vendor or service provider to ensure they can provide software, services, infrastructure, support, security, documentation, and compliance controls suitable for the intended GMP/GxP use.
Risk level	A qualitative classification of the AI tool or use case based on GxP impact, data sensitivity, system integration, record impact, decision impact, validation need, and potential harm if the AI output is incorrect.

6. Main Checklist Table

Completion Note

Mark one response for each question. If Yes indicates a possible GMP/GxP impact, document the control strategy in Comments / Justification. High-risk items require QA/Compliance/Validation/CSV review before use.

Section	Assessment Question	Yes	No	N/A	Risk Impact	Comments / Justification
Intended use	Has the intended use of the AI tool been clearly defined in writing?	[ ]	[ ]	[ ]	**Medium**	

Intended use	Is the AI tool limited to advisory support rather than autonomous GMP decision-making?	[ ]	[ ]	[ ]	**High**	
Intended use	Are prohibited uses clearly defined, such as batch release, final QA approval, final root cause conclusion, or regulatory filing decision without human approval?	[ ]	[ ]	[ ]	**High**	
Intended use	Are the user roles, workflows, departments, and business processes using the AI tool clearly identified?	[ ]	[ ]	[ ]	**Medium**	
GMP/GxP impact	Could the AI tool affect product quality, patient safety, GMP compliance, regulatory submissions, or the validated state of a system/process?	[ ]	[ ]	[ ]	**High**	
GMP/GxP impact	Will AI output be copied into, attached to, referenced by, or used to support a GMP record?	[ ]	[ ]	[ ]	**High**	
GMP/GxP impact	Could incorrect AI output lead to an incomplete investigation, weak CAPA, missed impact assessment, incorrect training, or misleading quality conclusion?	[ ]	[ ]	[ ]	**High**	
GMP/GxP impact	Is there a documented rationale if the AI tool is classified as non-GMP or low impact?	[ ]	[ ]	[ ]	**Medium**	
Data entered into AI system	Will users enter GMP records, batch data, deviation details, CAPA records, complaints, validation data, supplier data, or regulatory information into the AI tool?	[ ]	[ ]	[ ]	**High**	
Data entered into AI system	Will users enter confidential company information, trade secrets, formulations, methods, process parameters, or product-specific data?	[ ]	[ ]	[ ]	**High**	
Data entered into AI system	Will users enter personal data, employee data, patient information, adverse event data, or customer complaint information?	[ ]	[ ]	[ ]	**High**	
Data entered into AI system	Are input data sources controlled, approved, current, complete, and traceable?	[ ]	[ ]	[ ]	**High**	
Data entered into AI system	Is there a procedure or instruction defining what data may not be entered into the AI tool?	[ ]	[ ]	[ ]	**Medium**	
Output generated by AI system	Will the AI tool generate summaries, classifications, recommendations, risk scores, draft records, decision prompts, or investigation support content?	[ ]	[ ]	[ ]	**High**	
Output generated by AI system	Are AI outputs required to include source references, links, or traceability to supporting records?	[ ]	[ ]	[ ]	**High**	
Output generated by AI system	Can the AI output be reproduced or reconstructed later if needed for audit or inspection?	[ ]	[ ]	[ ]	**High**	
Output generated by AI system	Is there a process to identify and correct inaccurate, incomplete, biased, outdated, or hallucinated AI outputs?	[ ]	[ ]	[ ]	**High**	
Human review	Is trained human review required before any AI output is used in a GMP/GxP record or decision?	[ ]	[ ]	[ ]	**High**	
Human review	Are review responsibilities defined for QA, Validation, CSV, IT Quality, Compliance, Regulatory Affairs, or SMEs as applicable?	[ ]	[ ]	[ ]	**High**	
Human review	Can users accept, reject, modify, or override AI outputs with documented rationale?	[ ]	[ ]	[ ]	**High**	
Human review	Are final GMP decisions clearly assigned to authorized personnel and not to the AI tool?	[ ]	[ ]	[ ]	**High**	
Electronic records	Will the AI tool create, modify, maintain, retrieve, archive, transmit, or influence electronic GMP records?	[ ]	[ ]	[ ]	**High**	
Electronic records	Are AI-generated records or recommendations retained when they support GMP decisions?	[ ]	[ ]	[ ]	**High**	
Electronic records	Can the system distinguish between original source data, AI-generated content, and human-approved conclusions?	[ ]	[ ]	[ ]	**High**	
21 CFR Part 11	Has Part 11 applicability been assessed for the intended use?	[ ]	[ ]	[ ]	**High**	
21 CFR Part 11	If applicable, are controls in place for system validation, audit trails, access control, authority checks, record retention, and electronic signatures?	[ ]	[ ]	[ ]	**High**	
21 CFR Part 11	Are electronic signatures, approvals, or attestations linked to the correct record, user, meaning, date, and time?	[ ]	[ ]	[ ]	**High**	
ALCOA+	Are data attributable to the person/system that generated, reviewed, approved, or modified them?	[ ]	[ ]	[ ]	**High**	
ALCOA+	Are records legible, contemporaneous, original or true copy, accurate, complete, consistent, enduring, and available?	[ ]	[ ]	[ ]	**High**	
ALCOA+	Are AI outputs protected from undocumented alteration, deletion, overwriting, or uncontrolled regeneration?	[ ]	[ ]	[ ]	**High**	
Validation	Has the AI tool or AI-enabled function been assessed for validation requirements based on intended use and risk?	[ ]	[ ]	[ ]	**High**	
Validation	Are user requirements, functional requirements, data flows, test scripts, acceptance criteria, and validation summary defined where applicable?	[ ]	[ ]	[ ]	**High**	
Validation	Has the tool been tested using realistic GMP scenarios, including known false positives, false negatives, and incorrect outputs?	[ ]	[ ]	[ ]	**High**	
Validation	Is the AI model, configuration, prompt library, workflow, or algorithm version controlled?	[ ]	[ ]	[ ]	**High**	

Change control	Will implementation of the AI tool require change control?	[ ]	[ ]	[ ]	**Medium**	
Change control	Are model updates, vendor updates, data source changes, prompt changes, integration changes, or workflow changes controlled?	[ ]	[ ]	[ ]	**High**	
Change control	Is there a process to assess revalidation or regression testing after changes?	[ ]	[ ]	[ ]	**High**	
Supplier/vendor qualification	Has the AI vendor/provider been qualified or assessed based on intended GMP/GxP use?	[ ]	[ ]	[ ]	**High**	
Supplier/vendor qualification	Has the vendor provided documentation for security, data handling, validation support, uptime, change notification, model updates, and support?	[ ]	[ ]	[ ]	**High**	
Supplier/vendor qualification	Is it clear whether company data may be used to train external/shared models?	[ ]	[ ]	[ ]	**High**	
Cybersecurity	Has cybersecurity risk been assessed, including authentication, encryption, access control, logging, and data storage location?	[ ]	[ ]	[ ]	**High**	
Cybersecurity	Are integrations with QMS, DMS, LMS, LIMS, MES, ERP, CMMS, SCADA/historian, or other systems secured and approved?	[ ]	[ ]	[ ]	**High**	
Cybersecurity	Is there a response process for AI tool outage, breach, unauthorized access, or compromised output?	[ ]	[ ]	[ ]	**High**	
Confidentiality	Are confidentiality restrictions defined for product data, process data, supplier data, regulatory data, employee data, and patient/customer data?	[ ]	[ ]	[ ]	**High**	
Confidentiality	Are users trained not to enter restricted or sensitive information into public or uncontrolled AI tools?	[ ]	[ ]	[ ]	**High**	
Training	Have users been trained on approved AI use, prohibited use, data entry restrictions, output review, and escalation of errors?	[ ]	[ ]	[ ]	**Medium**	
Training	Are training records maintained for personnel using the AI tool in GMP/GxP workflows?	[ ]	[ ]	[ ]	**Medium**	
Periodic review	Is there a defined periodic review schedule for AI performance, access, changes, incidents, user feedback, and continued fit for intended use?	[ ]	[ ]	[ ]	**High**	
Periodic review	Are AI errors, missed signals, incorrect outputs, user overrides, complaints, deviations, or audit findings trended?	[ ]	[ ]	[ ]	**High**	
Periodic review	Is there a process to retire, restrict, or suspend AI use if performance, compliance, security, or vendor controls are no longer acceptable?	[ ]	[ ]	[ ]	**High**	

7. Risk Classification

Risk Level	Typical Criteria	Examples	Minimum Control Expectation
Low Risk	No GMP/GxP data entered. No regulated records created or modified. No influence on quality decisions. No integration with validated systems. Output used only for general awareness, brainstorming, or non-GMP drafting.	Public-domain learning, non-confidential brainstorming, generic grammar improvement for non-GMP content.	Manager/QA awareness may be sufficient. Users must avoid entering confidential or GMP data. Human review still required before reuse.
Medium Risk	AI supports GMP-adjacent or low-impact quality tasks with human review. Output may support drafting, searching, summarizing, or organizing information but does not directly determine GMP decisions. Limited or no system integration.	Draft SOP language for review, summarize approved procedures for training draft, search historical deviations for investigator awareness.	Documented risk assessment. Human review required. Procedure/training needed. Validation assessment required; validation may be limited based on intended use.
High Risk	AI uses GMP/GxP records, affects regulated decisions, connects to validated systems, creates/updates electronic records, influences investigations/CAPA/batch release/regulatory submissions, or could impact patient safety/product quality if wrong.	AI-supported batch review, AI risk scoring, AI complaint signal detection, AI-generated investigation conclusions, AI integrated with QMS/LIMS/MES/ERP.	Formal QA/CSV/Validation/IT Quality review. Change control and validation likely required. Supplier qualification, Part 11 assessment, data integrity controls, cybersecurity review, training, periodic review, and approval required.

8. Final Decision Section

Decision	Decision Rationale / Conditions
[ ] Approved for non-GMP use only	AI may be used only for non-GMP, non-confidential, non-regulated activities. No GMP records or quality decisions may rely on AI output.
[ ] Approved for GMP support with human review	AI may support defined GMP/GxP activities only within the approved intended use and with documented human review before use in records or decisions.
[ ] Requires validation before use	AI tool or workflow may not be used in the proposed GMP/GxP process until validation, required documentation, and approvals are completed.
[ ] Not approved for use	AI tool or intended use is not acceptable due to GMP, data integrity, confidentiality, cybersecurity, validation, supplier, or regulatory risk.

9. Required Documentation

Retain the following records as applicable based on risk level, intended use, and company procedures:

- Completed AI Tool GMP Risk Assessment Checklist
- Formal risk assessment or quality risk management record
- Validation plan, requirements, test evidence, traceability matrix, and validation summary report
- Part 11 / Annex 11 / data integrity assessment
- Vendor/supplier qualification records and vendor documentation
- Cybersecurity and privacy assessment
- Data flow diagram and source system inventory
- Change control record
- SOPs, work instructions, prompt/use instructions, or governance procedure
- Training materials and training records
- Approval record and final decision rationale
- Periodic review records, performance monitoring, incident logs, and AI output/error trend review

10. Approval Table

Role	Name	Department	Signature	Date	Comments
Prepared by					
Reviewed by - QA					
Reviewed by - Validation/CSV					
Reviewed by - IT Quality / Cybersecurity					
Reviewed by - Compliance / Regulatory Affairs					
Approved by					

11. 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.

12. Website Integration Block

Website Field	Recommended Content
SEO title	AI Tool GMP Risk Assessment Checklist | AIforQA.org
Meta description	Download a practical GMP checklist to assess AI tools for GxP use, validation, data integrity, Part 11, and human review.
Recommended URL slug	/tools/ai-tool-gmp-risk-assessment-checklist
Recommended tags	AI in QA; GMP; GxP; AI Risk Assessment; Part 11; Data Integrity; CSV; Validation; QMS; Compliance
Short website excerpt	Use this practical QA checklist to assess whether an AI tool can be used in GMP/GxP workflows and what controls are required before implementation.
Related AIforQA.org article ideas	What Happens When AI Makes a GMP Mistake?; AI for Pharmaceutical Risk Management Under ICH Q9; AI for GMP Document Review and Approval Workflows; AI for Change Control Impact Assessments; AI for Batch Record Review by Exception
Suggested internal links	/articles/ai-pharmaceutical-risk-management-ich-q9; /articles/what-happens-when-ai-makes-a-gmp-mistake; /articles/ai-gmp-document-review-approval-workflows; /articles/ai-change-control-impact-assessments; /articles/ai-batch-record-review-by-exception