

AI Change Control Impact Assessment Template

Professional GMP/Pharma QA Tool for AlforQA.org

Short Description

This template helps pharmaceutical QA, Validation, CSV, Compliance, IT Quality, Change Control Owners, and System Owners evaluate the quality, validation, data integrity, cybersecurity, training, and regulatory impact of AI-related changes in GMP/GxP environments.

1. Intended Use

- New AI tool implementation in a GMP/GxP or quality-system context.
- AI model updates, retraining, configuration changes, or prompt/workflow changes.
- Software version upgrades for AI-enabled systems.
- AI integrations with QMS, LMS, LIMS, MES, ERP, DMS, CMMS, EBR, or other regulated systems.
- Changes to how AI output is used, including movement from non-GMP support to GMP decision support.
- Vendor, cloud hosting, data storage, cybersecurity, or supplier-support changes.
- AI system retirement, decommissioning, replacement, or migration.

2. Scope

Scope Area	Description
Included	AI-related changes that may affect GMP/GxP processes, regulated records, quality decisions, validation state, data integrity, cybersecurity, training, vendor oversight, or regulatory commitments.
Excluded	General non-GMP brainstorming or administrative productivity use with no confidential, proprietary, patient, GMP, or quality-system data and no impact on official records or decisions. Exclusions should still follow company AI-use policy.

3. User Instructions

1. Enter the change information before implementation or prior to change-control approval.
2. Define the current state, proposed state, reason for change, intended use, and affected process clearly enough for QA and SMEs to evaluate impact.
3. Complete each impact assessment question by selecting Yes, No, or N/A. Add comments or evidence for all Yes responses and for any N/A that may be questioned during review.
4. Assign an impact level using company criteria or the risk classification section in this template.
5. Determine required actions, including validation, SOP revision, training, supplier review, cybersecurity review, and regulatory assessment.
6. Attach supporting evidence such as vendor documentation, risk assessment, validation plan, Part 11 assessment, data-flow diagram, or change-control record.
7. Obtain required review and approval before implementation unless company procedures allow emergency implementation with retrospective approval.
8. After implementation, confirm completion of required actions, including validation execution, training, SOP updates, and post-implementation review.

4. Key Definitions

Term	Definition
AI change	Any introduction, modification, upgrade, configuration change, model update, prompt/workflow change, integration change, hosting change, or retirement activity involving an AI tool or AI-enabled system.
Intended use	The approved purpose for which the AI system or output will be used, including the specific process, user group, data inputs, outputs, and decision context.
Impact assessment	A documented evaluation of how the proposed change may affect GMP/GxP processes, records, validation, data integrity, cybersecurity, training, suppliers, and regulatory obligations.
GxP impact	Potential effect on regulated activities, product quality, patient safety, data integrity, batch release, quality records, validation, or compliance decisions.
Validation impact	Potential effect on the validated state of a computerized system, process, model, interface, data flow, report, calculation, or workflow.
Data integrity impact	Potential effect on the completeness, consistency, accuracy, attribution, legibility, contemporaneousness, originality, availability, or traceability of data and records.
Model update	A change to an AI/ML model, algorithm, training data, configuration, weights, parameters, prompts, retrieval sources, or performance-monitoring settings.
Human oversight	Documented review, verification, challenge, acceptance, rejection, or approval of AI outputs by qualified personnel before use in a GMP/GxP context.
Change control	A formal quality-system process for assessing, approving, implementing, documenting, and verifying changes that may affect GMP/GxP processes or systems.

5. Change Information

Change Control Number		Change Title	
System/Tool Name		Change Owner	
Department		Vendor	
Current State		Proposed State	
Reason for Change		Affected Process	
Target Implementation Date		Related SOP/Procedure	
Related System ID		Related Validation Package	

6. Impact Assessment Checklist

Complete this checklist for the proposed AI-related change. Use the Impact Level field to classify each applicable impact as Low, Medium, High, or Critical based on company procedures and the risk classification section in this template.

Impact Area	Assessment Question	Yes	No	N/A	Impact Level	Required Action	Comments / Justification
GMP/GxP process impact	Could the change affect a GMP/GxP process, quality-system workflow, batch release activity, investigation, CAPA, change control, training, or compliance decision?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
GMP/GxP process impact	Could the change alter how AI output is used from administrative support to GMP-supporting or GMP-impacting use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
GMP/GxP process impact	Could the change affect product quality, patient safety, process control, or quality decision-making?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
SOP impact	Are any SOPs, work instructions, forms, templates, policies, or user guides affected by the change?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
SOP impact	Does the change require updates to AI-use procedures, system administration procedures, validation SOPs, or data governance procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Validation impact	Could the change affect the validated state of the AI system, connected system, interface, report, calculation, workflow, data pipeline, or model behavior?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Validation impact	Does the change require validation planning, regression testing, IQ/OQ/PQ, performance testing, or revalidation assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Validation impact	Could the change affect approved user requirements, functional requirements, configuration specifications, or acceptance criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Part 11 impact	Could the change affect electronic records, electronic signatures, audit trails, user access, record retention, report generation, or system validation controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Part 11 impact	Does the change require a new or updated 21 CFR Part 11 assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
ALCOA+ / data integrity impact	Could the change affect data attribution, legibility,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

Impact Area	Assessment Question	Yes	No	N/A	Impact Level	Required Action	Comments / Justification
	contemporaneousness, originality, accuracy, completeness, consistency, endurance, or availability?						
ALCOA+ / data integrity impact	Could AI-generated outputs be copied into or used to support GMP records without adequate source verification and human review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
ALCOA+ / data integrity impact	Could the change modify data sources, data transformations, retrieval sources, model outputs, or record retention expectations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Audit trail impact	Could the change affect audit trail generation, audit trail visibility, audit trail review, or the ability to reconstruct AI-assisted decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Audit trail impact	Will AI prompts, inputs, outputs, reviewer decisions, overrides, or approvals be retained where required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Electronic records/signatures	Could the change create, modify, maintain, retrieve, archive, transmit, summarize, or approve electronic GMP records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Electronic records/signatures	Could the change affect electronic signatures, approval workflows, signature meaning, or signature manifestation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Cybersecurity	Could the change affect user authentication, authorization, data transfer, encryption, cloud hosting, network security, APIs, or external access?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Cybersecurity	Does the change require IT security review, penetration testing, vendor security documentation, or cybersecurity risk assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Supplier/vendor qualification	Does the change involve a new vendor, new hosting model, changed support model, changed subcontractor, or changed AI/ML model provider?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Supplier/vendor qualification	Is updated vendor documentation, supplier qualification, quality agreement, SOC report, security questionnaire, or audit required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Training impact	Will users, reviewers, approvers, administrators, QA, validation, IT, or business process owners require training before implementation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

Impact Area	Assessment Question	Yes	No	N/A	Impact Level	Required Action	Comments / Justification
Training impact	Does training need to address AI limitations, human review expectations, prohibited data entry, and approved intended use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
QMS records	Could the change affect deviations, CAPAs, complaints, audits, training records, change controls, regulatory intelligence records, or other QMS records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
QMS records	Could AI outputs become supporting evidence for a GMP decision or quality-system record?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Batch records	Could the change affect batch records, electronic batch records, batch release review, review-by-exception, process monitoring, or product impact assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Batch records	Could AI output influence batch disposition, deviation triage, or batch review prioritization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Regulatory commitments	Could the change affect registered processes, approved submissions, inspection commitments, regulatory responses, market-specific requirements, or data submitted to agencies?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Regulatory commitments	Does Regulatory Affairs need to assess filing, notification, variation, supplement, or commitment impact?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Risk assessment	Has a risk assessment been completed or updated for the change and its intended use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Risk assessment	Have false positives, false negatives, overreliance, hallucinated output, model drift, and human oversight risks been assessed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Periodic review	Will the change affect periodic review scope, AI performance monitoring, model monitoring, metrics, or system health review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Periodic review	Are post-implementation monitoring criteria defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Rollback plan	Is a rollback, contingency, or disablement plan required if the AI change causes unacceptable performance, compliance, cybersecurity, or data integrity issues?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Rollback plan	Can users return to the prior approved process without losing required records or traceability?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

7. Risk Classification

Classification	Criteria	Typical Control Expectation
Minor AI change	Administrative or low-complexity change with no direct GMP record impact, no change to intended use, no change to model behavior affecting outputs, and no effect on validated state or regulated decisions.	Routine documented assessment; QA review as required by company procedure.
Moderate AI change	Change may affect configuration, workflow, prompts, retrieval sources, reporting, user access, training, or GMP-supporting output, but does not independently make GMP decisions.	Risk assessment; validation impact assessment; possible regression testing; SOP/training review.
Major AI change	Change affects intended use, model behavior, data sources, interfaces, GMP records, electronic records/signatures, quality decisions, or validated workflows.	Formal validation planning; Part 11/data integrity assessment; supplier/security review; QA approval before implementation.
Critical/high-risk AI change	Change may influence batch release, product impact assessment, regulatory decisions, deviation/CAPA conclusions, automated decision-making, or patient/product quality risk.	Formal cross-functional assessment; validation/revalidation; QA/CSV/RA/IT approval; enhanced monitoring; possible management approval.

8. Required Actions

Required Action	Selection	Details / Evidence
Validation required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	If yes, define validation package, testing scope, acceptance criteria, and approval requirements.
SOP revision required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	List affected SOPs, forms, work instructions, templates, and policies.
Training required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Define impacted roles, training type, completion deadline, and effectiveness check if needed.
Supplier review required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Attach vendor documentation, quality agreement updates, audit results, or supplier qualification evidence.
Cybersecurity review required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Attach security assessment, architecture review, cloud/hosting review, or vulnerability assessment as applicable.
Regulatory assessment required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Document RA evaluation of filing commitments, variations, supplements, market requirements, or inspection commitments.
Implementation approval required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Define approval gate before production/GMP use and required approvers.

9. Final QA Decision

Decision	Decision Criteria / Rationale
<input type="checkbox"/> Approved	The AI change may be implemented as assessed. Required actions must be completed according to the approved plan.
<input type="checkbox"/> Approved with conditions	The AI change may proceed only after listed conditions are completed and documented.
<input type="checkbox"/> Rejected	The AI change is not approved for implementation or GMP/GxP use. Document rationale.
<input type="checkbox"/> Additional assessment required	The change cannot be approved until additional QA, CSV, validation, IT, supplier, cybersecurity, or regulatory assessment is completed.
Final Decision Rationale	
Conditions / Required Follow-Up	
Implementation Hold Point	
Post-Implementation Review Due Date	

10. Required Documentation to Retain

- Completed AI Change Control Impact Assessment Template
- Approved change control record and implementation plan
- AI/GxP risk assessment or quality risk management record
- Validation impact assessment and validation plan, if applicable
- URS, functional requirements, configuration specifications, and test scripts, if applicable
- IQ/OQ/PQ, regression testing, model performance testing, or data integrity testing evidence, if applicable
- 21 CFR Part 11 / Annex 11 assessment, if applicable
- Data-flow diagram, interface assessment, audit trail assessment, and record-retention assessment, if applicable
- Supplier/vendor qualification documentation, security review, quality agreement, or vendor change notification
- SOP, form, training, and communication records
- Regulatory Affairs assessment, if applicable
- Rollback/contingency plan and post-implementation monitoring evidence
- Final approval record and signatures

11. Approval Table

Role	Name	Department	Signature	Date
Prepared by				
Reviewed by				
Approved by				

12. 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

Website Field	Recommended Content
SEO title	AI Change Control Impact Assessment Template for GMP Systems
Meta description	Assess GMP, validation, data integrity, cybersecurity, and regulatory impact of AI-related changes in pharma QA.
Recommended URL slug	/tools/ai-change-control-impact-assessment-template
Recommended tags	AI change control; GMP AI; pharmaceutical QA; CSV; validation; data integrity; quality systems; AI governance
Short website excerpt	Download a practical GMP/Pharma QA template for assessing AI-related changes, including validation, data integrity, Part 11, cybersecurity, supplier, training, and regulatory impact.
Related AlforQA.org article ideas	AI for Change Control Impact Assessments; What Happens When AI Makes a GMP Mistake?; AI Validation Readiness Assessment; AI in Pharmaceutical Knowledge Management; AI for GMP Document Review Workflows
Suggested internal links	/articles/ai-change-control-impact-assessments; /tools/ai-tool-gmp-risk-assessment-checklist; /tools/ai-validation-readiness-assessment; /tools/ai-generated-content-review-checklist; /tools/chatgpt-ai-use-log-for-qa-teams