PROCESS · GXP CLASSIFICATION

Classify AI Uses as GxP or Non-GxP with Quality

An OmniTek Consulting implementation guide for VPs and Directors in pharma, biotech, and medical device companies.

READING TIME	WHO IT'S FOR	GOES WITH
About 11 minutes	VPs and Directors	The AI Maturity Quick Check

> Classifying each AI use before it starts lets low-risk work move fast and puts validation effort where patient safety, product quality, and data integrity are actually at stake. Agree the rules with Quality once, and every new AI idea gets a clear path in days instead of months.

SCOPE This guide covers AI used in how your company works, such as drafting, analysis, and operations. It doesn't cover AI that is part of a product you sell, such as AI-enabled device software or software as a medical device. That has its own regulatory path; check it with your Regulatory team.

Why it matters

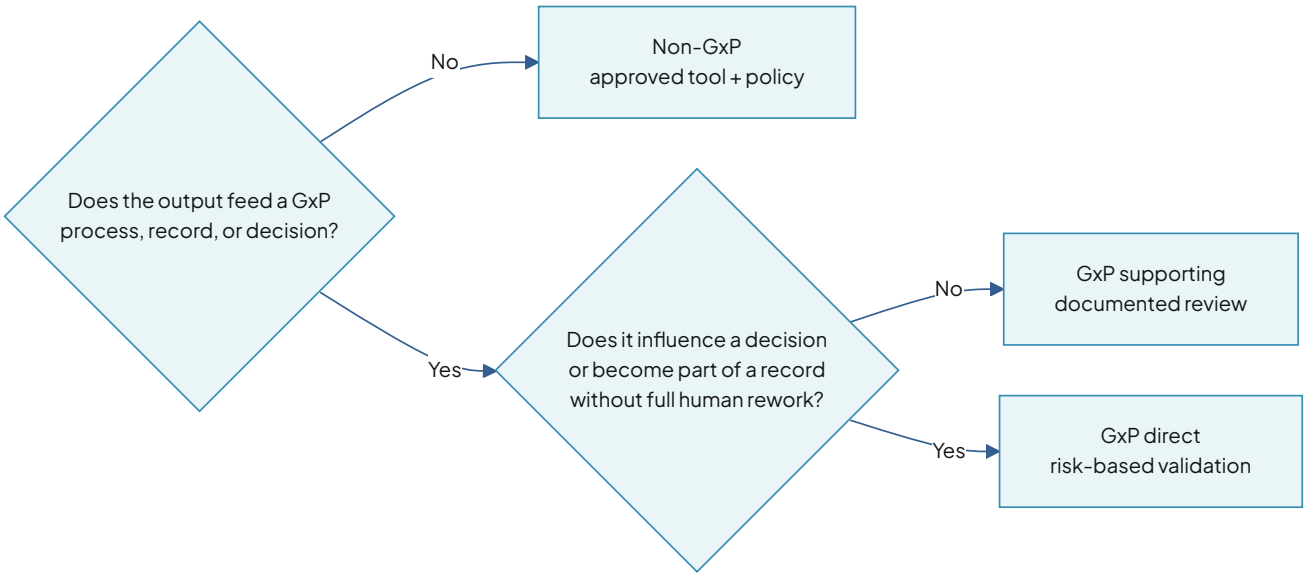
Without a shared way to classify AI uses, teams fall into one of two traps:

- **Everything is GxP.** Quality treats a meeting summary like a batch record. Every pilot needs full validation, nothing ships, and people quietly use personal tools instead.
- **Nothing is GxP.** AI drifts into regulated work, such as drafting deviation investigations or reviewing case reports, without anyone deciding it should. The first time it's examined is during an inspection.

A classification step fixes both. It is short, it is documented, and it is owned jointly by your department and Quality.

Three classes, two questions

Two questions sort every AI use into one of three classes; a few uses are not permitted without specific approval. Non-GxP, GxP supporting, and GxP direct are OmniTek's working terms to agree with Quality, not categories defined by regulators.



Class	What it means	Controls
Non-GxP	The output never reaches a regulated process, record, or decision.	Approved tool, the AI policy, use recorded
GxP supporting	The output feeds regulated work, but a qualified person reviews and owns every word or number before it is used.	Recorded classification, documented review against the source by a qualified owner, approved tool with supplier qualification scaled to risk, training recorded
GxP direct	The output influences a regulated decision or becomes part of a GxP record without full human rework.	Risk assessment, validation scaled to impact, change control, ongoing performance monitoring. Record-creating uses (such as adverse event coding or submission tables) add ALCOA+ data integrity controls; decision uses (such as CAPA selection) add a named human decision owner who is accountable
Not permitted / requires specific approval	The use belongs to a role that can't be handed to AI, such as batch release, or the output would be an uncontrolled GxP document.	Not used unless QA (or the QP for batch release) approves a documented exception

The test. A use is GxP supporting only if all four are true:

- A qualified person reviews every output against its source before it is used.
- That review is written into the procedure and recorded.
- The reviewer can fully check the output without AI. If checking every item isn't practical, for example a summary of hundreds of documents, it isn't supporting.
- The output doesn't become part of a GxP record or decision until the review is done.

If any of these fails, treat the use as GxP direct.

Examples by department.

Department	Non-GxP	GxP supporting	GxP direct	Not permitted / requires specific approval
Quality	Drafting a training session agenda	First draft of an SOP revision that goes through document control	Trending deviations to decide which become CAPAs	–
Clinical Operations	Summarizing a published paper for a team meeting	Drafting a monitoring visit letter the CRA rewrites and signs (the letter can contain subject information, so the data-privacy rules apply)	Flagging protocol deviations in trial data	–
Pharmacovigilance	Laying out a safety review slide (layout only, no data)	–	Coding adverse events in the safety database; suggesting search terms for a literature review, with the safety scientist approving and documenting the final search strategy, because the search decides which cases are found (GVP Module VI)	–
Manufacturing	Writing a shift handover email, where the handover isn't a controlled record	–	Recommending process adjustments	Recommending batch disposition (batch release is a QP or QA responsibility); summarizing an equipment manual for a technician, which without document control is an uncontrolled work instruction (acceptable only if the summary goes through document control and review against the source, as the Quality SOP draft does)
Regulatory Affairs	Tracking agency news	Drafting a response outline a writer completes	Generating data tables for a submission	–

GCP uses, such as the Clinical Operations examples, fall under ICH E6(R3), which encourages a risk-based and proportionate approach built on quality by design. In the EU, pharmacovigilance uses fall under GVP; GVP Module VI covers adverse reaction reports, including literature monitoring.

The draft EU GMP Annex 22 (consulted on July to October 2025, not yet final; status) would apply to AI used in critical GMP applications, meaning those with a direct impact on patient safety, product quality, or data integrity. It covers only static, deterministic models. It says models that keep learning during use, models whose outputs can differ for the same input, and generative AI or large language models should not be used in critical GMP applications. In non-critical uses, qualified people should confirm each output is suitable for its intended use. Until Annex 22 is final, treat generative AI as not suitable for GxP direct uses in GMP work.

Data sensitivity is a separate check from GxP class: patient or personal data, unblinded data, and trade secrets need their own check in every class (see the data protection guide).

When it's unclear, classify one level higher and revisit after a month of use.

A classification worksheet

One worksheet per AI use, completed by the requester and signed off by Quality. Most take 15 minutes.

TEMPLATE · COPY AND ADAPT

AI Use Classification

Use ID: [AI-YYYY-###] | Department: [ ] | Requester: [ ] | Date: [ ]

1. The use

What task will AI do? [one sentence] Which tool? [name, version or plan] Approved for this data class? [Yes / No] Who uses the output, and for what? [ ]

2. Question 1: Does the output feed a GxP process, record, or decision?

[ ] No -> Non-GxP. Skip to section 5. [ ] Yes -> Which one? [process, record, or decision; GMP / GCP / GLP / GVP / device QMS]

3. Question 2: Does it influence a decision or become part of a record without full human rework?

GxP supporting only if all four are true: [ ] A qualified person reviews every output against its source before it is used [ ] That review is written into the procedure and recorded [ ] The reviewer can fully check the output without AI [ ] The output doesn't become part of a GxP record or decision until the review is done [ ] All four true -> GxP supporting. Name the reviewer role: [ ] [ ] Any false -> GxP direct. Complete section 4.

4. GxP direct only

Impact if the output is wrong: patient safety [H/M/L], product quality [H/M/L], data integrity [H/M/L] Will the model change over time (retraining, vendor updates)? [ ] Validation approach and owner: [reference to validation plan] How performance will be monitored after go-live: [ ]

5. Sign-off

Class: [Non-GxP / GxP supporting / GxP direct] Requester: [name, date] Quality: [name, date] Review date: [ ]

Keep completed worksheets in one register. The register doubles as your AI inventory, which auditors and inspectors may ask about.

Your first 30 days

1. **Week 1: List current and planned AI uses.** Ask each team lead for the AI uses they have running or want to start. Include informal uses, not just official projects.
2. **Week 1: Agree the two questions with Quality.** Meet with your Quality partner, walk through this guide, and adjust the wording of the questions and classes to fit your quality system.
3. **Week 2: Classify the list together.** Run every use through the worksheet in one working session. Most will land in Non-GxP or GxP supporting, which is the point: those can proceed now.
4. **Week 3: Write it into a procedure.** Add the classification step to your computerized systems or validation SOP through change control, and reference it from your AI policy.
5. **Week 4: Open the front door.** Publish how to submit a new AI use, who signs off, and how quickly. A target of five working days for Non-GxP and GxP supporting uses keeps people from working around the process.

By day 30 you have a classified AI inventory, a written procedure, and a fast path for low-risk work. That should move you toward the Operationalizing level on the Quick Check's GxP classification question.

Common mistakes

- **Classifying the tool instead of the use.** The same tool can be Non-GxP for drafting an email and GxP direct for coding adverse events. Classify each use, not each product.
- **Letting "human in the loop" do too much work.** A reviewer who skims and approves isn't full human rework. If the output is used largely as-is, treat it as GxP direct.
- **No review date.** Uses drift. A summarizing tool becomes a decision aid within months. Revisit each classification at least yearly, and whenever the use or the tool changes.
- **Quality learns about it last.** Classification only works when Quality co-owns it from the first meeting. Present it as a way to say yes faster, not as a new hurdle.
- **Full validation for supporting uses.** GxP supporting uses usually need documented review and training, not a full validation package. Over-validating them is how pilots stall. The tool still needs supplier or tool qualification proportionate to risk, under EU GMP Annex 11 (suppliers and service providers) and your SOPs, documented as those SOPs require. Simplified qualification is still qualification.

Regulatory touchpoints

These classes are working terms, not regulatory categories. They apply the risk-based thinking in FDA's CSA guidance and ISPE GAMP to AI uses: define the intended use, then scale controls to the risk. Status is as of October 2026.

Source	Status	What it supports
FDA Computer Software Assurance guidance	Final. The current version (February 2026) is titled "Computer Software Assurance for Production and Quality Management System Software" and refers to FDA's Quality Management System regulation (21 CFR Part 820); written for device production and quality system software	Start from intended use and focus assurance on software whose failure could affect product quality or safety
ISPE GAMP 5 (Second Edition)	Published July 2022	A practical risk-based framework for GxP computerized systems used in pharma. It relies on critical thinking by experienced experts, discusses FDA's CSA approaches, and helps meet EU GMP Annex 11.
ISPE GAMP Guide: Artificial Intelligence	Published 2025	Risk-based, scalable life cycle activities for AI-enabled computerized systems, from concept through monitoring and change
EU GMP Annex 22 (AI)	Draft published for consultation in July 2025; not yet final (status)	Expectations for static, deterministic AI models in critical GMP applications; generative AI, large language models, and models that keep learning or give different outputs for the same input should not be used there
21 CFR Part 11	In force	GxP direct uses that create or change electronic records need Part 11 controls
ICH E6(R3) Good Clinical Practice	Final (Step 4). Principles and Annex 1 adopted January 2025; Annex 2 (decentralised and pragmatic elements, real-world data) adopted 3 June 2026; consolidated guideline adopted 16 June 2026	GCP uses, such as monitoring letters or protocol deviation flagging, follow a risk-based and proportionate approach focused on critical-to-quality factors
EU Good Pharmacovigilance Practices (GVP), Module VI	Module VI Rev 2 in effect since November 2017, with Addendum I (duplicate management, 2017) and Addendum II (masking of personal data in reports to EudraVigilance, effective 25 July 2025). EMA says GVP modules affected by ICH E2D(R1) will be revised; check for updates	PV uses, such as literature screening, sit within the EU rules for collecting, managing and submitting adverse reaction reports

This guide is general information, not legal or regulatory advice. Your Quality and Regulatory leads should confirm how these apply to your products and markets.

How OmniTek can help

Classification is where most life sciences AI programs either speed up or stall. The full AI Maturity Report Card looks at your department's GxP validation approach and comes with the **GxP classification kit**: an editable worksheet, a one-page decision tree, and a sign-off form for Quality.

To talk through your AI inventory or your Quick Check results, book time with OmniTek.

Book time with OmniTek

SOURCES

- FDA: Computer Software Assurance for Production and Quality Management System Software (final guidance, February 2026)
- ISPE GAMP Guide: Artificial Intelligence
- ISPE GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (Second Edition, July 2022)
- ISPE Pharmaceutical Engineering: New GAMP Guide addresses challenges posed by AI-enabled computerized systems (September–October 2025)
- European Commission: Stakeholders' consultation on EudraLex Volume 4, Chapter 4, Annex 11 and new Annex 22 (July–October 2025)
- eCFR: 21 CFR Part 11
- ICH E6(R3): Guideline for Good Clinical Practice, final version (adopted 6 January 2025)
- ICH E6(R3) Annex 2: Guideline for Good Clinical Practice (Step 4, adopted 3 June 2026)
- ICH E6(R3): Guideline for Good Clinical Practice, consolidated with Annex 2 (Step 4, adopted 16 June 2026)
- EMA: Good pharmacovigilance practices (GVP)
- EMA: GVP Module VI, Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2, effective 22 November 2017)

This guide is general information for leaders in regulated life sciences functions, not legal or regulatory advice. Confirm requirements with your Quality, Regulatory, and Legal teams. © 2026 OmniTek Consulting.