

AI Output Is Not Objective Evidence

AI-generated output may assist drafting, summarize information, support analysis, and suggest conclusions — but it should never be treated as objective evidence until verified.

What AI Can Do

- Assist drafting
- Summarize information
- Support analysis
- Suggest conclusions

What AI May Also Do

- Generate inaccurate information
- Omit important context
- Produce unsupported conclusions
- Present incorrect information confidently

Key Principle: If AI output cannot be reasonably verified, it should not be used to support regulated decisions. AI may provide suggestions — but humans remain accountable for regulated conclusions.





Not All AI Use Carries the Same Regulatory Risk

Understanding the context of AI use is essential. The closer AI gets to regulated decisions, controlled records, or validated systems, the greater the expectation for governance and procedural control.

AI Use Context	Typical Examples	Governance Expectation
General Productivity Use	Emails, brainstorming, formatting, notes	Review before use
Supporting Regulated Decisions	CAPAs, investigations, summaries, trend analysis, risk support	Governed review and verification process

Regulated Decisions Require structured governance and documented review	Controlled Records Demand procedural controls and verification	Validated Systems Carry the highest expectation for oversight
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AI Requires Consistent Governance

Because AI systems are indeterminate, outputs may vary, conclusions may be incomplete, reasoning may be unsupported, and errors may appear convincing. Organizations cannot rely on ad hoc review alone.

Why Procedures May Need to Change

Existing QMS procedures may need to define:

- Acceptable AI use cases
- Required review expectations
- Verification requirements
- Documentation expectations
- Approval responsibilities
- Risk-based review rigor

Important Clarification

AI does not replace existing QMS controls.

Organizations may need to extend existing controls to AI-assisted activities — not build entirely new systems from scratch.






Review Rigor Should Match Decision Impact

Not every AI-assisted output demands the same level of scrutiny. A risk-based approach ensures that review effort is proportional to the consequences of the decision being made.

Decision Impact	Example AI Use	Suggested Review Expectation
Low	Grammar, formatting, titles	Review
Medium	Summaries, descriptions, trend interpretation	Review + verification
High	Root cause analysis, CAPA actions, risk conclusions	Verification + documented justification

 Key Principle: All AI-assisted content should be reviewed — but not all requires the same level of verification or documentation. The purpose is to apply review rigor appropriate to the level of decision impact.

What Effective AI Governance Looks Like

Effective governance is not about controlling every AI output. It is about ensuring decisions remain consistent, defensible, appropriately reviewed, and governed by process.



Review

Detect obvious errors in AI-generated content before it enters any workflow



Verification

Confirm accuracy and completeness against source data or subject matter expertise



Justification

Support regulated conclusions with documented rationale



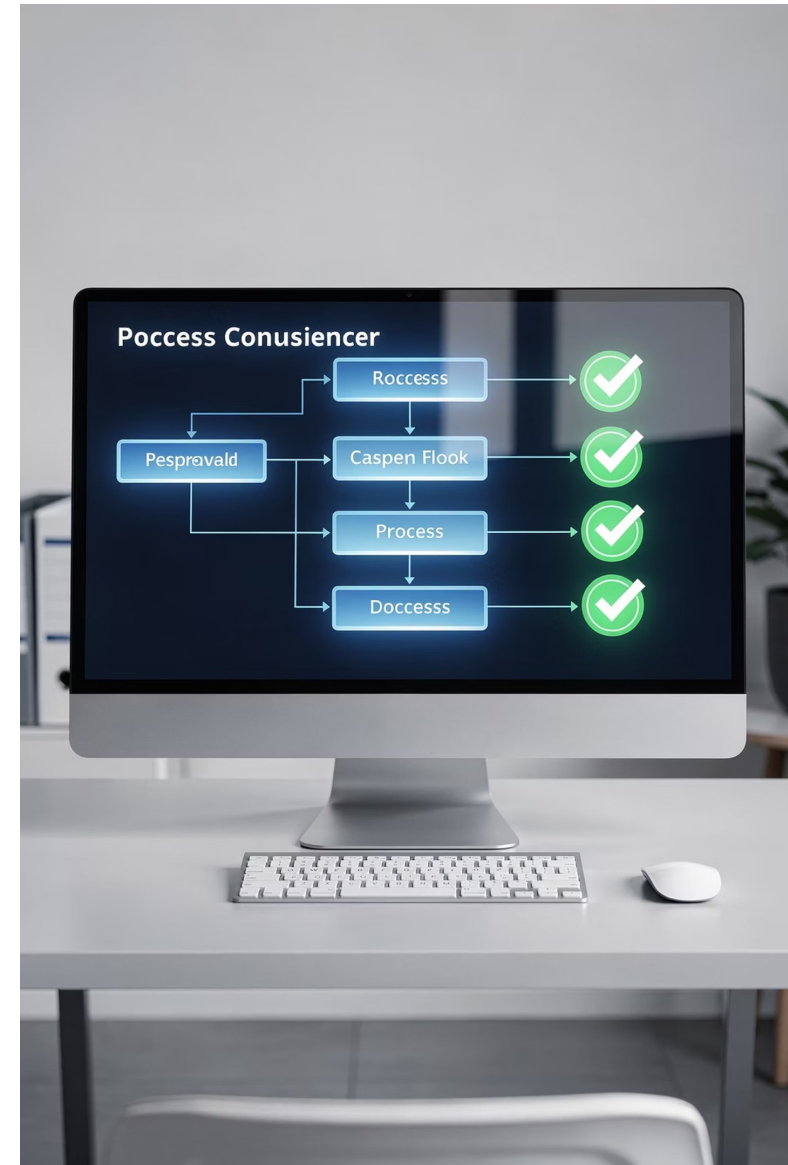
Procedures

Ensure consistent review expectations across the organization



Approval

Maintain accountability for all regulated decisions



AI Is Not the Risk. Unverified Decisions Are.

Before approving AI-assisted content, every reviewer should be able to answer these questions:

Is the information accurate?

Can you confirm the facts independently of the AI output?

Is the conclusion supported by evidence?

Does the reasoning trace back to verifiable data?

Is the reasoning defensible?

Would this conclusion hold up under regulatory scrutiny?

Is the review level appropriate?

Does the rigor match the impact of the decision being made?

Would the decision stand alone?

If the AI output were removed, would the decision still be supportable?

Final Principle: You are not controlling every AI output. You are controlling how AI output is used in your process.





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Bridging analytical rigor with practical application in quality management and regulatory compliance.

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NOTE: This guide is educational in nature and does not replace organization-specific regulatory, quality, legal, or cybersecurity review.

