

Let AI read and draft. Keep people deciding.

For quality, operations and IT teams choosing where AI may help with documents, questions and drafts, and proving who checks it.



Suggestions, not records

A read value counts only after a person checks it.

Test the hard cases

Decimals, units, missing values and poor scans.

Decisions stay human

Release, disposition and signatures belong to people.

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Who this is for

Quality and QC leads, operations managers, supplier quality, document control, IT and validation owners in food, supplement, pharmaceutical, device and chemical manufacturing.

Important. This guide helps you evaluate AI assistance. It is not legal advice and makes no claim that any product, including V5, complies with a law or framework. Your procedures and your intended use decide what is acceptable.

How to use it. List your uses on page 3, build the test pack on page 9 from your own documents, and send the vendor pages 10 and 12 a week before the demonstration.

1 • SCOPE

Where AI helps, and where it stops

Write down each use. For each one: what the AI produces, who checks it, and what decision follows.

USE	AI PRODUCES	CHECKED BY	DECISION THAT FOLLOWS (HUMAN)
Supplier certificate	Values read from the PDF or photo	QC analyst, against the page	Lot release by quality
Delivery note / label photo	Item, lot, quantity read	Receiving operator	Accept or reject the receipt
AP invoice	Lines matched to PO and receipt	Accounts payable	Approve payment
Deviation	Suggested category and CAPA draft	Quality owner	Classify, investigate, close
Reorder	Suggested purchase order	Buyer	Place or change the order
Formula draft	Draft from a target spec	Technical lead	Approve the master formula
Daily brief / question	Summary and pointer to records	The reader	Whatever the record requires

1. Extract or draft

The AI reads a document or writes a draft.



2. Review

A named person checks it against the source and confirms, corrects or rejects.



3. Decide

A separate, authorised decision: release, approve, close.

Keep step 3 separate. A signed review of extracted values is not a lot release. Your procedure should say who can release and on what evidence.

2 • BOUNDARIES

Available now vs coming soon

Ask every vendor to mark each AI feature as available, in preview or planned, in writing.

IN V5 TODAY (PRODUCTION REFERENCE, 27 SEP 2026)	PLAN
V5 Assistant: find screens and workspace records	All plans
Help AI: answers about your own setup and documents	All plans
Daily Brief AI: overnight summary and what needs attention	All plans
Formula AI and Vision AI / OCR for labels, CoAs and delivery notes	All plans
CoA extraction, Doc Intake, Invoice, Quality, Reorder and Scorecard AI	Professional and Enterprise
Audit-trail explainer and Report Builder assistant	Professional and Enterprise
COMING SOON — NOT AVAILABLE TODAY	WHAT TO DO NOW
Demand and yield forecasting	Plan with your current planning method; don't buy on it
Anomaly detection on process data and scale streams	Keep your existing limits, checks and alarms

Provider access. In V5, AI features need configured provider access for your workspace, and every output needs human review.

Permissions. The assistant does not remove role or workspace boundaries. Test that by asking as a user without access.

3 • WORKED EXAMPLE

Reading a supplier certificate

Citric acid, receiving lot RM-7741, supplier lot B-22817, specification SPEC-CA-03 rev 4.
Example data.

Certificate (source)

Assay 99.7 %

Moisture 0,4 %

Sulphated ash < 0.05 %

Particle size 30-60 mesh

(no lead result printed)

FIELD	READ AS	REVIEWER
Assay	99.7 %	Confirmed
Moisture	4 %	Corrected to 0.4 %
Sulphated ash	0.05 %	Corrected to < 0.05 %
Particle size	30-60 mesh	Confirmed (not a spec item)
Lead	Not found	Requested from supplier

ERROR TYPE	WHAT HAPPENED	WHY IT MATTERS
Decimal comma	0,4 read as 4	A pass becomes a fail, or worse, the reverse on another field
Qualifier dropped	< 0.05 read as 0.05	A limit result becomes a measured value
Unit	mg/kg vs ppm vs %	Wrong unit can shift a value by 10,000
Missing value	Lead not printed	Must stay blank and be chased, never inferred

Outcome. Review signed: 2 confirmed, 2 corrected, 1 missing. The lot stays in quarantine. Quality decides release after the lead result arrives.

4 • EVIDENCE

Source vs suggestion evidence

An inspector or auditor should be able to see what the AI suggested, what the person changed and why.

KEEP FOR EACH FIELD	EXAMPLE
Source document and page	CoA B-22817, page 1
Value as read	Moisture 4 %
Value as confirmed	0.4 %
Change reason	Decimal comma misread
Reviewer and time	QC analyst A. Ng, 2 Oct 09:12
Specification version	SPEC-CA-03 rev 4
Downstream decision	Release by QA after lead result (separate record)

Ask to see in the demo

CHECK	WHAT GOOD LOOKS LIKE	OK
Original beside suggestion	The reviewer sees the page, not only the extracted list	☐
Edits are recorded	Changed values keep the original suggestion and the reason	☐
Missing stays missing	No default value is filled in	☐
Rejection is possible	A whole extraction can be rejected and entered manually	☐

Metrics. Measure your own correction rate during the pilot (fields corrected ÷ fields reviewed). Don't rely on a vendor accuracy figure measured on other documents.

5 • DECISIONS

Reviewer decision matrix

Agree in advance what a reviewer does in each case. Put this in your procedure.

SITUATION	REVIEWER ACTION	ESCALATE TO	LOT STATUS
Read value matches source and is in spec	Confirm	—	Unchanged until release decision
Read value differs from source	Correct, with reason	—	Unchanged
Source value out of spec	Confirm value as printed	Quality: deviation or reject	Held
Value missing from source	Leave blank; request from supplier	Supplier quality	Held
Source unreadable	Reject extraction; request a clean copy	Supplier quality	Held
Wrong document attached	Reject extraction	Receiving	Held
Spec version unclear	Stop	Document control	Held

Training. Reviewers need the same training as for manual entry, plus the error types on page 5.

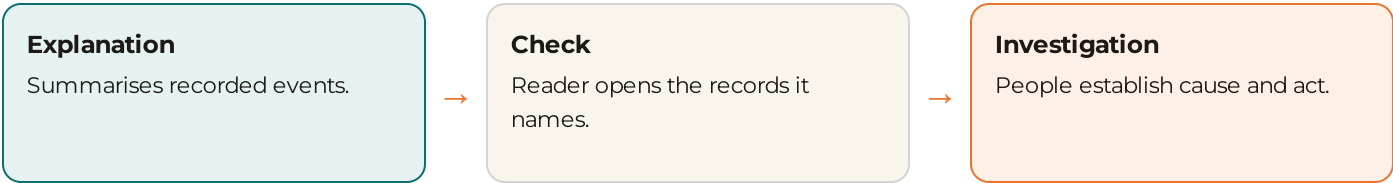
Never automatic. Don't configure any path where an AI output alone changes material status, signs a record or closes a deviation.

Assistants, briefs and explanations

Question-answering features need a different test: does the answer point to records you can open and check?

EXAMPLE QUESTION	GOOD ANSWER	READER STILL DECIDES
Why is lot P-0412 on hold?	Hold H-2291 placed 06:14 by J. Ortiz; 06:00 check missing; 07:00 passed	Release, extend or open a deviation
What needs me today?	Short list with links to each record	Priorities
Why did batch 118 deviate?	Audit-trail events in order, with who and when	Root cause and CAPA
Build a report of holds by line	A draft report definition	Whether the report is correct

Explanation vs investigation



Test for confident wrong answers. Ask about a lot that doesn't exist, and about records the user isn't allowed to see. A good assistant says it can't find or show them.

7 • TESTING

Challenge-case test pack

Build twelve cases from your own documents. Run them in the demo and again before go-live.

#	CASE	EXPECTED OUTCOME
1	Clean typed certificate	All values read; reviewer confirms
2	Decimal comma (0,4)	Read correctly or caught at review
3	Less-than result (< 0.05)	Qualifier kept
4	Mixed units (ppm and mg/kg)	Units shown; no silent conversion
5	Missing analyte	Shown as missing, not filled
6	Phone photo at an angle	Read or flagged unreadable
7	Two lots on one certificate	Values tied to the right lot
8	Wrong supplier's certificate	Mismatch visible to reviewer
9	Handwritten correction on the page	Flagged for the reviewer
10	Question about a non-existent lot	Says it cannot find it
11	Question by a user without access	No restricted data shown
12	Provider unavailable	Manual entry still possible

Record results. Case, date, result, who ran it. Re-run after any provider, model or configuration change (page 11).

Provider and data questions

Ask in writing. Don't assume where data is processed, how long it's kept or whether it's used for training.

QUESTION	WHY IT MATTERS	ANSWER RECEIVED
Which AI providers process our data?	Your supplier list and contracts	
In which regions is it processed?	Data location requirements	
Is our data used to train models?	Confidentiality	
How long are prompts and outputs kept?	Retention policy	
Can AI features be switched off per feature?	Control and fallback	
Who is notified when the provider or model changes?	Change control	
What happens when the provider is down?	Continuity	
Which security documents can you share?	Your own assessment	

No assumptions in this guide. It does not state V5's data location, retention or training terms. Ask us for current written answers and your contract terms.

Intended use, change control and fallback

Write a one-page intended-use statement for each AI use, then test to the risk.

STATEMENT	EXAMPLE: CERTIFICATE READING
Intended use	Suggest values from supplier CoAs for QC review
Not intended for	Releasing lots or replacing testing
Users	Trained QC analysts
Risk if wrong	Mis-recorded result; mitigated by full review
Assurance	Test pack page 9, plus review of first 50 documents
Fallback	Manual entry from the certificate
Change trigger	Provider, model, prompt or configuration change

Medical-device production and QMS software. FDA's Computer Software Assurance guidance (final, 3 Feb 2026) gives non-binding recommendations for a risk-based approach to production and quality system software. Device makers may find it useful; it is not an approval route for AI and doesn't cover every sector.

Voluntary frameworks. NIST's AI Risk Management Framework 1.0 (26 Jan 2023, being revised) and its Generative AI Profile (AI 600-1, 26 Jul 2024) are voluntary. There is no certification against them.

Other markets have their own rules; check those that apply to your products and sites. In V5, IQ/OQ support is available on Enterprise only.

Demonstration plan and scorecard

Ninety minutes with your documents. Send these a week ahead.

#	SCENARIO	WATCH FOR	
1	Read three of your certificates, including cases 2–5	Original beside suggestion; edits recorded	
2	Reject one extraction and enter it manually	Manual path works; nothing auto-filled	
3	Ask the assistant about a held lot	Answer names records you can open	
4	Ask the same as a restricted user	Nothing restricted shown	
5	Show where AI is switched off	Per-feature control and who can change it	
6	Show forecasting and anomaly detection status	Clearly marked as not yet available	

AREA	WHAT TO SEE DEMONSTRATED	SYSTEM A	SYSTEM B
Source visibility	Reviewer always sees the source next to the suggestion	_____	_____
Edit evidence	Original suggestion, change and reason kept	_____	_____
Separation	Review and release are separate decisions	_____	_____
Honest status	Available vs planned stated in writing	_____	_____
Provider answers	Page 10 answered in writing	_____	_____
Fallback	Manual path demonstrated	_____	_____
Total (0–3 each)		_____	_____

First month, V5 fit and sources

WEEK	DO	EVIDENCE
1	Intended-use statements; switch on one use only	Signed statements
2	Run the test pack; train reviewers	Test log, training records
3	Live use with full review	Correction rate measured
4	Review results; decide next use	Review minutes

- **V5:** AI suggestions land in the record they support for a person to confirm, correct or reject. AI does not release lots or sign records. Features need configured provider access; outputs need human review.
- **Plans:** assistant, Help, Daily Brief, Formula and Vision AI in every plan; CoA, Doc Intake, Invoice, Quality, Reorder, Scorecard AI, audit-trail explainer and Report Builder in Professional and Enterprise. Forecasting and anomaly detection: coming soon.

Sources explain buyer questions; they are not V5 compliance claims. Links reviewed 2 October 2026.

Voluntary frameworks

- **NIST AI Risk Management Framework (AI RMF 1.0, 26 Jan 2023; being revised)** — www.nist.gov/itl/ai-risk-management-framework
- **NIST AI 600-1 Generative AI Profile (26 Jul 2024)** — nvlpubs.nist.gov/nistpubs/ai/NIST.AI.600-1.pdf

Guidance (medical-device production and QMS software)

- **FDA Computer Software Assurance guidance page (3 Feb 2026)** — www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software
- **FDA CSA guidance PDF** — www.fda.gov/media/188844/download

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