

From document draft to human-controlled quality.

A detailed customer solution guide explaining how TrialVerity can reduce repetitive review effort, surface errors earlier, support controlled corrections, accelerate document finalization and preserve review evidence.

AI finds and proposes. Humans decide. TrialVerity records what happened.

1 Prepare & Ingest

Upload, classify and confirm document type

Add a new document

Choose File TrialVerity_Demo_DVP.docx

Title
Design Verification Plan (DVP) — Demo Device

Document Type
Design Verification Plan (DVP)

Data Sensitivity
Standard (Non-PII)

Upload Document

Authors upload existing documents (DOCX/PDF), confirm the document type and data sensitivity, and register a version in TrialVerity. The original document remains unchanged.



Customer value

- Works with your existing authoring process
- Explicit sensitivity classification and human confirmation

2 Govern with a Review Standard

Controlled, versioned review rules

Review Standard — Design Verification Plan (DVP)

Version 1.0 (Published)

Overview Review Rules Required Sections Severity Rubric

Review rules (excerpt)

- R-001 Verify each verification activity has a linked requirement identifier.
- R-002 Check for TBDs, placeholders, or incomplete criteria.
- R-003 Identify subjective pass/fail language.
- R-004 Validate consistency of numeric ranges and units.
- R-005 Ensure all required sections are present.

Quality teams control what the AI is asked to check through a published, versioned Review Standard. Rules, required sections, severity criteria and cross-document expectations are configurable.



Customer value

- Governed and versioned review criteria
- No hard-coded rules for each document type

3 Run AI Review

Structured output with strict validation

UNVALIDATED MODEL OUTPUT — NOT YET VALIDATED FINDINGS

VERSIONS

Choose File No file chosen

Upload as new version & re-run

Version: 1 (TrialVerity_Demo_DVP.docx) Download content
Status: completed - parser docx-v1 - 14 block(s)
Title: Design Verification Plan (DVP) — Demo Device
SYNTHETIC DEMONSTRATION DOCUMENT
NOT FOR REGULATORY USE

TrialVerity validates the model response against a strict structured schema. If the output does not conform, it is not promoted into findings and is clearly labeled as unvalidated.



Customer value

- AI is not trusted blindly
- Invalid model output does not become a finding

4 Findings with Evidence

Five issues found, with safe edit placement

All severities All categories

Showing 5 of 5 finding(s)

Previous Finding 4 of 5 Next

- Conflicting pressure range values for REQ-100 — high / consistency - Δ - Accepted
- Verification Activity VA-2 missing linked requirement identifier - high / traceability - Δ - Accepted
- Unresolved TBD in acceptance criterion for VA-3 — high / completeness - $\checkmark$ - Modified
- Subjective and non-verifiable pass/fail criterion for VA-4 — high / clarity - $\checkmark$ - Accepted
- Unresolved placeholder in approval section - medium / completeness - $\checkmark$ - Rejected

TrialVerity identifies issues such as inconsistent values, missing requirement links, TBDs, subjective criteria, and placeholders. Each finding is grounded in source evidence and assessed for safe edit placement.



Customer value

- Find problems earlier
- Evidence-backed findings, not unsupported conclusions

5 Human Review and Disposition

Accept, Reject or Modify each finding

Finding 3 of 5

Details Evidence Proposed Change Disposition

Unresolved TBD in acceptance criterion for VA-3

Severity high Category completeness

AI proposed change

Replace "TBD" with a specific, objective, and measurable acceptance...

Your disposition

Accept Reject ☒ Modify

Modified text (required)

Acceptance criterion for VA-3: result shall be within specification limits defined in REQ-103.

Reviewers examine each finding, view evidence, and decide to Accept, Reject, or Modify. Reviewer modifications are used in the reviewed redline (after human review completion).



Customer value

- Qualified people remain in control
- All decisions are recorded with a clear audit trail

6 Word Redlines

AI Proposed and Human-Reviewed

Home Insert Draw Design Layout References Mailings Review

Color Image Thumbnails Word Theme Name Computer

Design Verification Plan (DVP) — Demo Device
SYNTHETIC DEMONSTRATION DOCUMENT
NOT FOR REGULATORY USE

2. Verification Activities
Verification Activity VA-3 has no linked requirement identifier.
Acceptance criterion for VA-2: result shall be within specification limits (defined in REQ-103).
Replace with an objective criterion such as "Pressure if specific value is within defined range" or "Pressure if measurable outcome meets stated standard or specification".

TrialVerity AI Review Deleted: Acceptance criterion for VA-3: result TBD.
TrialVerity AI Review Deleted: Pass/fail criteria for VA-4: acceptable results are satisfactory.

TrialVerity can generate Word tracked-change artifacts for safely placed edits. After all findings are reviewed, a separate Human-Reviewed Redline reflects accepted and modified changes, excluding rejected and unplaced edits.



Customer value

- Familiar Microsoft Word review experience
- Supports faster, more efficient document finalization

7 Audit History and Provenance

Reconstruct what happened

Artifact details

Status: completed - Document version: 90e3493f-6885-4f90-9a80-02183bba9a6e
Checksum: 6dca88943099f347bde607f82ae0f51074f72590aac5ee94e645c4e6a7b
Storage: s3
Status: excluded_unplaced - Reason: ambiguous_target
Status: excluded_unplaced - Reason: unsupported_edit_operation - Block: b0009

Download Word review copy

TrialVerity preserves the review run, model/configuration provenance, placement results, reviewer dispositions and generated artifacts. A completed review run is preserved separately, supporting history rather than overwriting it.



Customer value

- Reconstructable audit evidence
- Supports internal and regulatory review

Measurable Business Value



Reduce review effort

Automate repetitive first-pass quality checks.



Catch issues earlier

Identify inconsistencies, missing criteria, traceability gaps and placeholders.



Reduce rework

Address issues earlier, with fewer comment cycles.



Accelerate finalization

Move from findings to reviewed redlines faster.



Preserve human control

Qualified reviewers make the final decisions, with a complete review trail.

Supported Document Families



Design & Requirements

- PRD - SRS - Design Specifications
- Trace Matrices



Verification & Validation

- DVP - QVR - V&V Protocols/Reports
- Software V&V



Manufacturing & Qualification

- Validation Plans/Reports
- IQ - OQ - PQ



Clinical & Regulatory

- Clinical Plans/Reports
- CER - Regulatory Documents



Post-Market & Quality

- PMS - PSUR - CAPA
- Related Quality Documentation

Executive Summary

TrialVerity is an AI-assisted quality document review and correction platform designed for regulated and quality-sensitive documentation. Its objective is not simply to have AI read documents. Its objective is to reduce avoidable manual search, repetitive review effort, downstream rework, comment-resolution cycles and audit reconstruction effort while preserving human authority over the final decision.

The platform applies a published, versioned Review Standard for the confirmed document type; evaluates the document and linked references; returns structured, evidence-backed findings; computes whether proposed edits can be placed safely; allows qualified reviewers to Accept, Reject or Modify each finding; supports controlled Word redlines; and preserves review history and provenance.

Core promise

AI finds and proposes. Humans decide. TrialVerity records what happened.

Business objectives

1. Minimize review time Automate repeatable first-pass quality checks and organize findings for reviewer disposition.	2. Reduce new manual errors Use governed rules, evidence grounding and deterministic placement boundaries rather than uncontrolled rewriting.
3. Accelerate finalization Connect detection, correction, human review, redline generation and re-review in one workflow.	4. Lower operational effort Reduce repetitive search, reconciliation, late rework and audit-history reconstruction where the pilot demonstrates value.

Important claims discipline

TrialVerity should be positioned as controlled assistance, not autonomous quality approval. Customer-specific savings, compliance posture and regulatory validation should be measured and established for the customer's intended use.

1. The Customer Problem

Controlled documents are created and maintained across product development, verification and validation, manufacturing and facility qualification, clinical activities, regulatory work and post-market surveillance. Manual review is time-consuming, and quality defects can become expensive when discovered late.

Repeated manual passes Authors, peers, SMEs and Quality may inspect the same content repeatedly for completeness and consistency.	Late defect discovery Missing criteria, placeholders or contradictions discovered near approval can trigger additional correction cycles.
Traceability burden Requirement references and relationships across documents can be difficult to verify manually.	Comment reconciliation Review comments and corrections may be spread across documents, email, Word and quality systems.
Unsafe automation risk Generic AI can rewrite text without the controls needed for quality-sensitive documentation.	Audit reconstruction Teams may later need to determine what version was reviewed, against what criteria, what changed and who decided.

The economic hypothesis

If meaningful issues can be found earlier, if reviewers spend less time searching for routine defects, if proposed corrections are easier to evaluate, and if review history is preserved automatically, the organization may reduce review effort and downstream rework while shortening the path from draft to review-ready documentation. TrialVerity treats this as a measurable pilot hypothesis rather than a guaranteed savings claim.

2. The TrialVerity Operating Model



Stage	What TrialVerity does	Human boundary
Prepare	Registers and ingests the document; captures sensitivity and document type.	User confirms context before AI review.
Govern	Pins the review to a published, versioned Review Standard.	Quality team controls what the AI is asked to check.
Review	Runs AI-assisted review and validates the response against a structured contract.	Invalid model output is not promoted into validated findings.
Ground	Connects findings to source evidence and determines safe edit placement.	If TrialVerity cannot locate a change safely, it does not guess.
Decide	Presents findings, evidence and proposed corrections.	Reviewer Accepts, Rejects or Modifies.
Redline	Creates controlled Word tracked-change artifacts from safely placeable changes.	Original source remains unchanged; human decisions govern reviewed output.
Audit	Retains run/config/model/activity metadata and exportable evidence.	History supports reconstruction; it is not itself an electronic signature or approval.

3. Step-by-Step Customer Workflow

The following workflow explains how TrialVerity connects customer objectives to concrete controls and actions.

1. Upload and register

Author uploads DOCX/PDF. TrialVerity registers the source and document version.

Operational effect: Avoids losing the source artifact and establishes version history.

2. Set sensitivity

Authorized user designates the document sensitivity before AI processing.

Operational effect: Creates an explicit governance gate for sensitive processing.

3. Confirm document type

TrialVerity can suggest a type; the user confirms or overrides it.

Operational effect: Prevents silent AI governance decisions.

4. Retrieve Review Standard

The confirmed type is linked to an active, published Review Standard.

Operational effect: Makes review criteria controlled, explicit and versioned.

5. Run AI review

TrialVerity evaluates the document against the configured rules and linked context.

Operational effect: Automates repetitive first-pass inspection.

6. Validate output

Model output must satisfy the expected structured contract before becoming findings.

Operational effect: Prevents malformed AI output from silently entering the workflow.

7. Ground findings

Findings show source evidence and location information.

Operational effect: Reduces reviewer search effort and improves explainability.

8. Determine placement

TrialVerity checks whether a proposed correction can be safely located.

Operational effect: Reduces risk of changing the wrong text.

9. Human disposition

Reviewer Accepts, Rejects or Modifies each finding and can record notes.

Operational effect: Keeps qualified people in control.

10. Produce redline

Safely placeable, disposition-appropriate changes can become native Word tracked changes.

Operational effect: Fits familiar controlled-document review practices.

11. Upload revised version

The revised document can be registered as a new version and reviewed again.

Operational effect: Supports iterative improvement without overwriting history.

12. Reconstruct history

Quality/Audit can inspect versions, runs, Review Standards, findings and human decisions.

Operational effect: Reduces later reconstruction effort.

4. How TrialVerity Reduces Error Risk

The platform is designed around the idea that useful AI must operate inside explicit boundaries. This matters because faster document review has little value if automation introduces new uncontrolled errors.

No autonomous approval AI findings remain recommendations. Final review and approval authority stays with qualified customer personnel.	No invented engineering facts A missing requirement reference can be flagged without fabricating the missing requirement identifier.
No unsafe edit placement If source text cannot be located reliably, the correction is surfaced as unplaced rather than inserted by guesswork.	Structured output validation Model output is validated before it becomes a governed finding.
Evidence grounding Reviewers see the source evidence supporting a concern rather than only a conclusion.	Reversible human decisions Accept, Reject and Modify keep reviewer judgment explicit and traceable.
Why this matters	The customer goal is not maximum automation. It is useful automation with controlled failure modes: detect early, explain clearly, propose carefully, and stop when human judgment is required.

5. Controlled Review Standards

A central differentiator is that TrialVerity does not rely on one uncontrolled generic AI prompt. Review behavior can be governed by document type through a versioned Review Standard.

Configuration area	Purpose
Governing standards / references	Customer-approved standards or references applicable to the document type.
Required sections	Expected content that should be present.
Review rules / common errors	Document-specific checks and known failure patterns.
Severity rubric	Guidance for prioritizing findings.
Style rules	Controlled expectations for clarity and quality language.
Linked-document expectations	Relationships and consistency checks across related documents.
Examples / provenance	Approved references, source/version information and SME-confirmation state.

Operational value

Quality teams can evolve review criteria through controlled configuration rather than requiring a new hard-coded review engine for every document type. Published versions preserve historical provenance so later review reconstruction can identify which criteria were in force.

6. Findings, Evidence and Controlled Corrections

A useful quality-review result is more than a list of AI comments. TrialVerity is designed to connect the issue, source evidence, severity, proposed correction and placement status so the reviewer can make a faster, better-informed decision.

Finding What TrialVerity believes requires attention.	Evidence The source content and location supporting the concern.
Severity Configured prioritization guidance for reviewer attention.	Proposed correction A suggested remediation where the source supports one.
PLACED TrialVerity can safely identify where a proposed change belongs.	UNPLACED The issue may be valid, but TrialVerity will not guess where to insert the correction.

Example: missing traceability

If a verification activity has no linked requirement, TrialVerity can identify the traceability problem. But it should not invent a requirement identifier. The correct human action may be to determine the appropriate requirement and then supply or modify the correction.

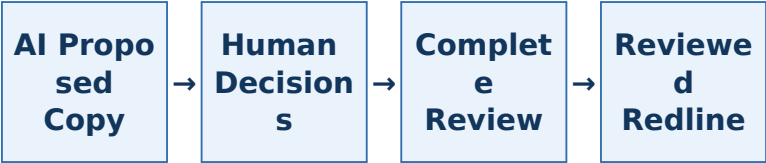
Example: unresolved acceptance criterion

If a localized TBD appears where an objective acceptance criterion is required and the source location is unambiguous, TrialVerity can flag the issue and safely locate the text for a proposed tracked correction.

7. Human Review and Word Redlines

Human intervention is a control, not an exception. Reviewers inspect findings and evidence and explicitly decide what should happen.

Accept Confirm that the finding/recommendation is valid for the review context.	Reject Record that the finding should not be acted on.	Modify Replace or refine the AI-proposed correction with reviewer-controlled wording.
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Two artifacts, two meanings

AI Proposed Review Copy: represents what the AI proposed from safely placeable changes.
Human-Reviewed Word Redline: represents the outcome after reviewer dispositions, so rejected suggestions are excluded and reviewer modifications can govern the final tracked-change wording.
Keeping these concepts distinct improves audit clarity.

Familiar workflow	Native Word tracked changes reduce change-management burden because reviewers can work with a familiar review mechanism rather than a proprietary rewrite format.
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7A. Human Decisions Control the Outcome

TrialVerity keeps the reviewer in control after AI review. Each finding can be **Accepted**, **Rejected**, or **Modified**. Human review can be completed only after every finding has a recorded disposition.

2026-09-16T01:22:40.891Z · completed · Human review: Not yet completed

Run status: **completed**

Re-run as new review

Creates a separate AI review using the same pinned inputs. Existing findings, reviewer decisions, audit history, and review copies remain unchanged.

► Review details

VALIDATED STRUCTURED FINDINGS

REVIEW SUMMARY
Document: Design Verification Plan – Synthetic Demo
AI review: **Completed** · Human review: **Ready to complete**
5 finding(s) requiring review · 3 safely located change(s) · 2 not safely located
5 of 5 finding(s) reviewed · Accepted: 3 · Rejected: 1 · Modified: 1 · Not yet reviewed: 0

Complete human review

► REVIEW AUDIT TRAIL

Production workflow: all five findings have reviewer decisions before completion.

Completion is a review milestone - not document approval

When the reviewer completes human review, TrialVerity records that the review is complete while explicitly preserving the distinction between review completion and document approval.

REVIEW RUNS

Latest — 2026-09-16T10:57:42.178Z · completed · Human review: Not yet completed

2026-09-16T01:22:40.891Z · completed · Human review: Not yet completed

Run status: **completed**

Re-run as new review

Creates a separate AI review using the same pinned inputs. Existing findings, reviewer decisions, audit history, and review copies remain unchanged.

► Review details

VALIDATED STRUCTURED FINDINGS

REVIEW SUMMARY
Document: Design Verification Plan – Synthetic Demo
AI review: **Completed** · Human review: **Completed**
5 finding(s) requiring review · 3 safely located change(s) · 2 not safely located
5 of 5 finding(s) reviewed · Accepted: 3 · Rejected: 1 · Modified: 1 · Not yet reviewed: 0
✓ Human review completed. This does not mean the document, or any proposed change, has been approved.

► REVIEW AUDIT TRAIL

The interface states that human review is complete without implying document or change approval.

7B. From AI Proposal to Human-Reviewed Redline

TrialVerity deliberately maintains two different Word artifacts. The **AI Proposed Word Review Copy** shows safely placeable AI-proposed edits. After human review is completed, the separate **Reviewed Word Redline** reflects the reviewer's dispositions.

AI PROPOSED WORD REVIEW COPY

This is a review copy. No proposed change is approved until a person reviews it.

The Word review copy contains AI-proposed tracked changes. Reviewer decisions above are recorded separately and do not change this file. Once human review is complete, a separate Reviewed Word Redline below reflects those decisions.

3 proposed change(s) were added to the Word review copy as tracked changes. 2 proposed change(s) were not inserted because TrialVerity could not locate them safely.

Download Word review copy

► Artifact details

REVIEWED WORD REDLINE

This reflects your human decisions above: accepted, safely-located proposed changes are included as written; modified findings use your own replacement text instead; rejected findings are excluded; and anything TrialVerity could not safely locate is never inserted, no matter the decision. This is not an electronic signature and does not approve the document.

Generate Reviewed Word Redline

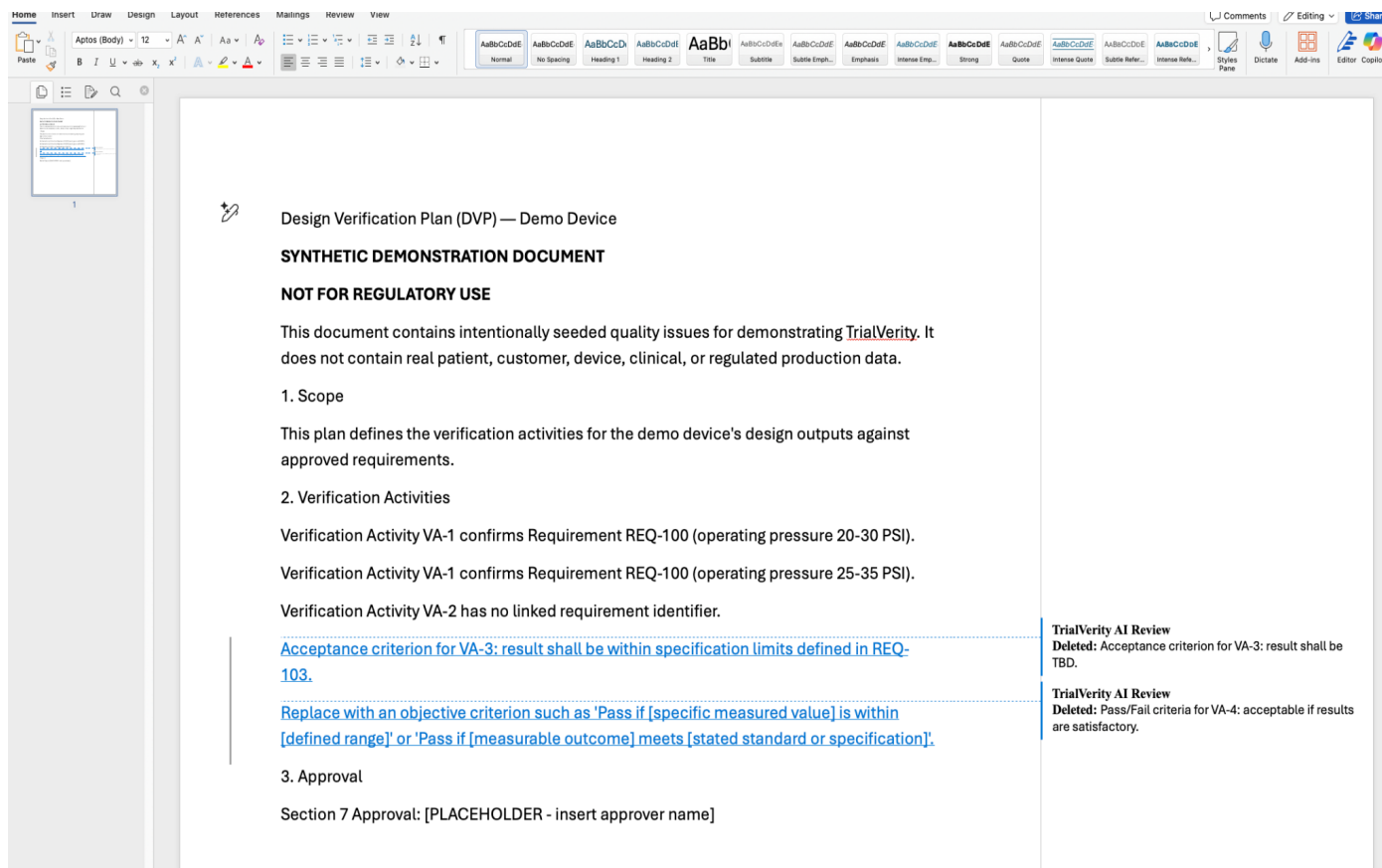
The reviewed-redline action is separate from the earlier AI-proposed review copy.

Reviewer decision	Reviewed Word Redline behavior
Accepted	Included when the proposed change can be safely located.
Modified	Uses the reviewer's replacement wording when safely located.
Rejected	Excluded from the reviewed redline.
Unsafe / unplaced	Not inserted automatically, regardless of disposition.

Production demonstration result: the AI-proposed review copy contained three tracked changes. After human dispositions, the Reviewed Word Redline contained two tracked changes - demonstrating that the reviewer decisions control the reviewed artifact.

7C. Native Microsoft Word Tracked Changes

The reviewed artifact opens in Microsoft Word using native tracked changes. This lets quality teams continue working in a familiar review environment while preserving the human-controlled outcome.



Synthetic demonstration: the reviewer-modified VA-3 correction and accepted VA-4 correction appear as tracked changes. The rejected approval-placeholder correction remains unapplied.

AI proposes. Humans decide.

Accepted, safely located changes can flow into the reviewed redline; modified findings use reviewer-controlled wording; rejected findings are excluded; and TrialVerity does not automatically insert a change it cannot safely locate.

Customer takeaway: TrialVerity assists with detection and correction while keeping qualified reviewers responsible for final decisions. Review completion and tracked-change generation do not constitute document approval or an electronic signature.

8. Linked Documents and Cross-Document Consistency

Many quality problems are not visible inside a single document. TrialVerity can link related documents and apply governed cross-document rules to identify configured inconsistencies and traceability problems.

Illustrative synthetic example

Document	Requirement	Value
Verification Plan / DVP	REQ-100	40 C
Linked Requirements document	REQ-100	45 C

Individually, each statement may appear plausible. The inconsistency becomes visible when the linked documents are evaluated together. Earlier detection can reduce downstream reconciliation and traceability correction effort.

9. Personas and Jobs-to-Be-Done

Persona	Primary job in TrialVerity
Document Author / Engineer	Prepare review-ready documents, run review, correct issues and work with redlined output.
Quality Reviewer	Inspect evidence-backed findings; Accept, Reject or Modify; complete human review.
Quality Manager / Quality Admin	Control document types, Review Standards, versions and quality workflows.
Clinical / Regulatory Specialist	Apply configured completeness and consistency review to clinical/regulatory documents.
Design / V&V; Engineer	Review SRS, DVP, trace matrices and protocols for traceability and consistency.
Manufacturing / Validation Engineer	Review IQ/OQ/PQ and validation documentation for missing criteria and inconsistencies.
Auditor / Compliance Lead	Inspect review history, provenance, dispositions and available evidence.
Organization Admin	Manage users/roles and operational processing controls.

Four simple product entry points

Review a Document Authors, engineers and specialists.	Review AI Findings Quality reviewers and SMEs.
Manage Review Standards Quality admins and SMEs.	See What Happened Quality managers, auditors and validation/compliance personnel.

10. Document Coverage

The common configuration model is designed to extend across multiple regulated-document families. Exact rules and standards should be configured and validated with the customer's subject-matter experts.

Family	Examples
Requirements & Design	PRD, Design Specification, SRS, Trace Matrix
Verification & Validation	DVP, DVR, Software Verification & Validation reports
Manufacturing / Qualification	Manufacturing Validation Plan/Report, IQ/OQ/PQ Protocols and Reports
Regulatory & Clinical	Regulatory Plan, Clinical Plan/Report, Clinical Evaluation Plan/Report
Post-Market	PSUR, PMS Plan, PMS Report
Extensible	Risk management, usability engineering, CAPA, DHF and other controlled types through governed configuration.

11. Operational Value Map

Current friction	TrialVerity mechanism	Potential business effect
Manual first-pass review	AI checks controlled rules and required sections	Less repetitive reviewer effort; faster issue discovery
Traceability gaps	Evidence-backed traceability findings	Fewer late-stage linkage corrections
Inconsistent values	Consistency and linked-document checks	Earlier detection of contradictions
Subjective acceptance language	Clarity/objectivity checks	More testable and reviewable criteria
Unresolved TBDs	Completeness checks	Fewer incomplete documents reaching approval
Unsafe AI edits	Deterministic placement gate	Lower risk of AI changing the wrong text
Comments across tools	Structured dispositions + audit trail	Less reconciliation and audit-prep effort
Word-based quality workflow	Native tracked-change artifacts	Lower user change-management burden

Potential business effects are hypotheses to validate during a pilot, not guaranteed outcomes.

12. Pilot and ROI Measurement Framework

A compelling design-partner pilot should use 2-3 customer-approved, non-sensitive document types and measure both quality and operational outcomes.

Step	Pilot activity
1	Baseline current review time and common defect/rework categories.
2	Create a controlled evaluation set with known or seeded defects.
3	Configure customer-approved Review Standards.
4	Run TrialVerity and measure detection, false positives, severity usefulness and evidence quality.
5	Measure reviewer time to Accept, Reject or Modify findings.
6	Measure how many proposed edits are safely placeable and useful in Word.
7	Measure downstream comment cycles or rework avoided where feasible.
8	Review audit-trail usefulness with Quality/Compliance stakeholders.
9	Use results to decide which document types and integrations should expand next.

Suggested KPI scorecard

Review time First-pass and total reviewer hours per document.	Quality Known/seeded issue detection and false positives.
Human effort Time to disposition findings and complete review.	Correction usability Safe placement rate and usefulness of Word redlines.
Rework Late defects, comment cycles and revisions where measurable.	Audit effort Time and completeness of review-history reconstruction.

13. Governance, Security and Scope Boundaries

Area	TrialVerity approach / boundary
Human authority	AI assists with review and correction; qualified users retain final review and approval authority.
Traceability	Review activity remains linked to document/version, applicable Review Standard and run history.
Sensitive processing	Sensitivity is explicitly designated and processing can be gated. Customer deployment requirements remain use-case specific.
AI reliability	Malformed model output or unsafe correction placement should be surfaced rather than silently promoted or inserted.
Validation	Appropriate computer-system-validation and regulatory controls depend on intended use and customer quality processes.
Compliance claims	Auditability features support regulated workflows but do not by themselves establish Part 11, Annex 11, HIPAA, GDPR or other compliance.

14. Customer Conversation Framework

A TrialVerity conversation should begin with the customer's operational bottleneck, not a feature tour.

Discovery questions

- Which document types consume the most Quality or Engineering review time?
- Where are errors usually discovered - during authoring, formal review, validation, approval or audit?
- How many review/comment cycles are typical?
- Which checks are repetitive enough to standardize?
- How is cross-document traceability verified today?
- How are reviewer decisions and audit evidence reconstructed later?
- Which document types would make the safest and highest-value pilot?

Recommended close

Pilot question

The question is not whether AI can read a document. It is whether this controlled workflow can reduce review time and catch meaningful issues earlier without giving up the controls the customer's quality process requires.

Source basis

This guide consolidates TrialVerity's Customer Workflow Story, Personas & Customer Use Cases, Proposed Solution & Implementation Roadmap, and 30-Step Customer Demo Guide. It intentionally preserves the platform's documented human-control and claims boundaries.