

COMPLIANCE WORKING RECORD

GxP system validation evidence pack

FICTIONAL evidence sample. Requires tailoring.

Document control

Field	Value
Document type	Evidence workpaper
Document reference	CASE-FICTIONAL
Jurisdiction	United States
Version	2026-10-09.product-sector.1
Status	FICTIONAL sample. Requires tailoring.
Classification	Private
Prepared by	Fictional responsible reviewer
Prepared on	October 9, 2026
Sources reviewed	October 9, 2026
Generated	October 9, 2026

Document control and frozen case

Assemble intended-use requirements, approved protocols, exact executed results, deviations and qualified current system-review evidence.

Field	Value
Case reference	CASE-FICTIONAL
Organization	Fictional Example Company
Subject	Fictional product or sector case
Responsible reviewer	Fictional responsible reviewer
Preparation date	October 9, 2026

Field	Value
Scope	Fictional customer-approved scope. Replace all example records before real use.
Customer policy	POLICY-FICTIONAL
Customer policy version	fictional-v1
Declared approver	Fictional qualified reviewer
Declared approval date	October 2, 2026
Decision boundary	No substantive decision or external filing made.

Named method and supported scope

Trace each requirement to exact protocol/system versions and latest executed records. Check approval chronology, literal criteria where selected, original result hashes, same-date conflicts and source-supported deviation closure.

FDA CSA reference supports medical-device production/QMS software only. Other predicate rules need customer-authorized exact sources. No live tests, validation certification or system release. Up to 100 rows per table, 20 originals and 25,000,000 combined original bytes. Complete oversized comparisons reject rather than truncate.

Original contents, annotations, approvals and legal applicability remain customer declarations. File hashes establish retained byte identity only.

No certificate issuance, environmental filing, recall notification, test execution, clinical decision, regulatory submission or independent certification occurs.

All accepted records remain complete. Recovery preserves original bytes and frozen results without creating fresh payment, source authentication, consent or approval authority.

Complete result counts

Measure	Value
Requirements with unresolved validation evidence	0
Current customer release review	Supported customer assertion

Complete preparation draft

Draft only. Unresolved positions remain explicit. No communication is sent.

System validation evidence preparation. No system-release authority created.

System. SYSTEM1. fictional-v1

Intended use. FICTIONAL intended quality-system use

Customer-selected predicate rule. FICTIONAL customer-selected predicate requirement

Complete approved requirement/protocol traceability.
[{"reference":"REQ1","sourceIds":["S1"],"requirement":"FICTIONAL preserve the exact record","riskRationale":"FICTIONAL approved record-integrity risk","protocolIds":["PROTOCOL1"],"approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-02"}]

Every executed result. [{"reference":"EXEC1","sourceIds":["S1"],"protocolReference":"PROTOCOL1","protocolVersion":"fictional-v1","systemReference":"SYSTEM1","systemVersion":"fictional-v1","executedOn":"2026-10-03","executor":"Fictional tester","actual":"FICTIONAL preserved","outcome":"Passed","sha256":"09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609"}]

Every deviation and exact closure record.
[{"reference":"DEV1","sourceIds":["S1"],"executionReference":"EXEC1","exactDeviation":"FICTIONAL documented observation","impact":"FICTIONAL qualified impact review","status":"Closed","correctiveAction":"FICTIONAL reviewed and recorded","closureEvidenceIds":["S1"],"closedOn":"2026-10-04","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-04"}]

Current human release review. [{"reference":"REVIEW1","sourceIds":["S1"],"systemVersion":"fictional-v1","position":"Approved","rationale":"FICTIONAL qualified release review, no actual authority","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-04"}]

Unresolved requirement count. 0

1. Original evidence source (S1)

State. Customer verification linked

Customer-declared original identity and verification only. Content is not extracted or independently authenticated.

Field	Value
id	S1
fileId	F1
locator	Fictional section one
sourceDate	October 1, 2026

Field	Value
custodian	Fictional customer custodian
description	Fictional source declaration. Does not establish actual evidence.
verification	Customer verified
verifiedBy	Fictional reviewer
verifiedOn	October 2, 2026
Exact evidence source references	S1

2. Original byte manifest (F1)

State. Indexed

Complete export requires these exact original bytes.

Field	Value
id	F1
name	FICTIONAL-product-sector-evidence.txt
mimeType	text/plain
bytes	220
sha256	09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609
Exact evidence source references	S1

3. Frozen customer policy (POLICY-FICTIONAL)

State. Documented

Exact approved customer scope. No automatic legal applicability.

Field	Value
reference	POLICY-FICTIONAL
version	fictional-v1

Field	Value
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026
sourceIds	["S1"]
Exact evidence source references	S1

4. Protocol execution and deviation traceability (PROTOCOL1)

State. Customer execution records linked

The tool assembles executed customer evidence. It does not run tests or certify validation.

Field	Value
reference	PROTOCOL1
sourceIds	["S1"]
version	fictional-v1
systemReference	SYSTEM1
systemVersion	fictional-v1
requirementReference	REQ1
method	FICTIONAL literal record equality check
checkMode	Literal equality
expected	FICTIONAL preserved
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026
Every exact execution	[{"reference":"EXEC1","sourceIds":["S1"],"protocolReference":"PROTOCOL1","protocolVersion":"fictional-v1","systemReference":"SYSTEM1","systemVersion":"fictional-v1","executedOn":"2026-10-03","executor":"Fictional tester","actual":"FICTIONAL preserved","outcome":"Passed","sha256":"09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609"}]

Field	Value
Latest exact executions	[{"reference":"EXEC1","sourceIds":["S1"],"protocolReference":"PROTOCOL1","protocolVersion":"fictional-v1","systemReference":"SYSTEM1","systemVersion":"fictional-v1","executedOn":"2026-10-03","executor":"Fictional tester","actual":"FICTIONAL preserved","outcome":"Passed","sha256":"09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609"}]
Every deviation	[{"reference":"DEV1","sourceIds":["S1"],"executionReference":"EXEC1","exactDeviation":"FICTIONAL documented observation","impact":"FICTIONAL qualified impact review","status":"Closed","correctiveAction":"FICTIONAL reviewed and recorded","closureEvidenceIds":["S1"],"closedOn":"2026-10-04","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-04"}]
Exact evidence source references	S1

5. GxP requirement-to-protocol traceability (REQ1)

State. Customer evidence traceability assembled

Predicate-rule applicability, acceptable assurance rigor and system release remain qualified customer decisions.

Field	Value
reference	REQ1
sourceIds	["S1"]
requirement	FICTIONAL preserve the exact record
riskRationale	FICTIONAL approved record-integrity risk
protocolIds	["PROTOCOL1"]
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026

Field	Value
Every selected protocol	[{"reference":"PROTOCOL1","sourceIds":["S1"],"version":"fictional-v1","systemReference":"SYSTEM1","systemVersion":"fictional-v1","requirementReference":"REQ1","method":"FICTIONAL literal record equality check","checkMode":"Literal equality","expected":"FICTIONAL preserved","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-02"}]
Gaps	
Exact evidence source references	S1

6. Validation deviation record (DEV1)

State. Customer deviation assertion

All deviation impacts, corrections and closure records remain visible.

Field	Value
reference	DEV1
sourceIds	["S1"]
executionReference	EXEC1
exactDeviation	FICTIONAL documented observation
impact	FICTIONAL qualified impact review
status	Closed
correctiveAction	FICTIONAL reviewed and recorded
closureEvidenceIds	["S1"]
closedOn	October 4, 2026
approvedBy	Fictional qualified reviewer
approvedOn	October 4, 2026
Exact evidence source references	S1

Complete accepted task inputs

The following exact accepted fields preserve every supplied task record, including orphan records and contradictions. They are customer annotations, not independently extracted or authenticated evidence.

Field	Value
systemReference	SYSTEM1
systemVersion	fictional-v1
intendedUse	FICTIONAL intended quality-system use
predicateRule	FICTIONAL customer-selected predicate requirement
requirements 1. reference	REQ1
requirements 1. sourceIds	S1
requirements 1. requirement	FICTIONAL preserve the exact record
requirements 1. riskRationale	FICTIONAL approved record-integrity risk
requirements 1. protocolIds	PROTOCOL1
requirements 1. approvedBy	Fictional qualified reviewer
requirements 1. approvedOn	October 2, 2026
protocols 1. reference	PROTOCOL1
protocols 1. sourceIds	S1
protocols 1. version	fictional-v1
protocols 1. systemReference	SYSTEM1
protocols 1. systemVersion	fictional-v1
protocols 1. requirementReference	REQ1
protocols 1. method	FICTIONAL literal record equality check
protocols 1. checkMode	Literal equality
protocols 1. expected	FICTIONAL preserved
protocols 1. approvedBy	Fictional qualified reviewer

Field	Value
protocols 1. approvedOn	October 2, 2026
executions 1. reference	EXEC1
executions 1. sourceIds	S1
executions 1. protocolReference	PROTOCOL1
executions 1. protocolVersion	fictional-v1
executions 1. systemReference	SYSTEM1
executions 1. systemVersion	fictional-v1
executions 1. executedOn	October 3, 2026
executions 1. executor	Fictional tester
executions 1. actual	FICTIONAL preserved
executions 1. outcome	Passed
executions 1. sha256	09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609
deviations 1. reference	DEV1
deviations 1. sourceIds	S1
deviations 1. executionReference	EXEC1
deviations 1. exactDeviation	FICTIONAL documented observation
deviations 1. impact	FICTIONAL qualified impact review
deviations 1. status	Closed
deviations 1. correctiveAction	FICTIONAL reviewed and recorded
deviations 1. closureEvidenceIds	S1
deviations 1. closedOn	October 4, 2026
deviations 1. approvedBy	Fictional qualified reviewer
deviations 1. approvedOn	October 4, 2026

Field	Value
reviews 1. reference	REVIEW1
reviews 1. sourceIds	S1
reviews 1. systemVersion	fictional-v1
reviews 1. position	Approved
reviews 1. rationale	FICTIONAL qualified release review, no actual authority
reviews 1. approvedBy	Fictional qualified reviewer
reviews 1. approvedOn	October 4, 2026

Recovery and original attachment boundary

The complete local ZIP includes every original file listed in the retained manifest. A structured JSON or cloud record alone preserves the descriptor and annotation, not the original file bytes. Attach matching bytes before producing a complete original-attachment pack.

Customer recovery restores neither source authentication, approval authority nor paid export access. Payment ownership is checked before each commercial export.

Official sources

Source	Provision	Date	Link
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Source	Provision	Date	Link
Food and Drug Administration: Computer Software Assurance for Production and Quality Management System Software. February 2026	FDA's February 2026 final guidance supersedes its September 2025 guidance and supports risk-based assurance for medical-device production and QMS software. It supports intended-use/protocol/result traceability within that scope only. Other GxP predicate rules require exact customer-authorized sources and qualified decisions. No validation certification or system release is inferred.	October 9, 2026	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software