

COMPLIANCE WORKING RECORD

Electronic record control assessment preparation

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

Organize exact system/version access, audit-trail, signature manifestation and record-control evidence within a customer-selected predicate-rule scope.

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

Map approved controls to latest source-linked observations with same-date conflict handling. Join authorized actors, exact record versions/hashes and signature manifestations. Preserve unsupported identities and human scope decisions.

No Part 11 compliance certificate, actual privilege inspection, tamper-proof audit trail, signature creation or authenticated recipient event. 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
Controls with unresolved evidence	0
Fresh authenticated signature authority	Not created

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

4. Electronic record control evidence (CONTROL1)

State. Customer control review linked

FDA Part 11 scope and predicate-rule decisions remain qualified customer decisions. Literal equality does not certify a system.

Field	Value
reference	CONTROL1
sourceIds	["S1"]
category	Access
provision	FICTIONAL current control provision
exactRequirement	FICTIONAL authorized access evidence
required	Yes
method	Literal equality
expected	FICTIONAL authorized
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026

Field	Value
Every supplied observation	[{"reference":"OBS1","sourceIds":["S1"],"controlReference":"CONTROL1","systemReference":"SYSTEM1","systemVersion":"fictional-v1","on":"2026-10-03","actual":"FICTIONAL authorized","reportedOutcome":"Passed","reviewer":"Fictional qualified reviewer","rationale":"FICTIONAL supplied observation"}]
Exact latest observations	[{"reference":"OBS1","sourceIds":["S1"],"controlReference":"CONTROL1","systemReference":"SYSTEM1","systemVersion":"fictional-v1","on":"2026-10-03","actual":"FICTIONAL authorized","reportedOutcome":"Passed","reviewer":"Fictional qualified reviewer","rationale":"FICTIONAL supplied observation"}]
Gaps	
Exact evidence source references	S1

5. Customer access authorization (ACCESS1)

State. Customer authorization recorded

This record does not authenticate the identity or inspect actual privileges.

Field	Value
reference	ACCESS1
sourceIds	["S1"]
identity	PERSON1
role	Fictional reviewer
authorized	Yes
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026
Gaps	
Exact evidence source references	S1

6. Supplied audit-trail event (AUDIT1)

State. Customer event indexed

No complete audit trail, tamper resistance or authenticated event is inferred from supplied annotations.

Field	Value
reference	AUDIT1
sourceIds	["S1"]
recordReference	RECORD1
recordVersion	fictional-v1
actor	PERSON1
on	October 3, 2026
event	Fictional review record
priorSha256	
newSha256	09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609
Every exact actor declaration	[{"reference":"ACCESS1","sourceIds":["S1"],"identity":"PERSON1","role":"Fictional reviewer","authorized":"Yes","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-02"}]
Gaps	
Exact evidence source references	S1

7. Signature manifestation and record linkage (SIGN1)

State. Imported/customer signature assertion linked

The application does not create or authenticate an electronic signature. Imported provider assertions remain source assertions.

Field	Value
reference	SIGN1
sourceIds	["S1"]
recordReference	RECORD1

Field	Value
recordVersion	fictional-v1
recordSha256	09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609
signer	PERSON1
printedName	Fictional reviewer
on	October 3, 2026
meaning	Fictional review approval
sourceKind	Customer record
authenticationReference	Fictional source authentication reference. Not application-authenticated.
Every exact record event	[{"reference":"AUDIT1","sourceIds":["S1"],"recordReference":"RECORD1","recordVersion":"fictional-v1","actor":"PERSON1","on":"2026-10-03","event":"Fictional review record","priorSha256":"","newSha256":"09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609"}]
Gaps	
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
predicateRule	FICTIONAL qualified predicate-rule selection
scopeDecision	Customer confirmed
scopeRationale	FICTIONAL current qualified scope decision
controls 1. reference	CONTROL1

Field	Value
controls 1. sourceIds	S1
controls 1. category	Access
controls 1. provision	FICTIONAL current control provision
controls 1. exactRequirement	FICTIONAL authorized access evidence
controls 1. required	Yes
controls 1. method	Literal equality
controls 1. expected	FICTIONAL authorized
controls 1. approvedBy	Fictional qualified reviewer
controls 1. approvedOn	October 2, 2026
observations 1. reference	OBS1
observations 1. sourceIds	S1
observations 1. controlReference	CONTROL1
observations 1. systemReference	SYSTEM1
observations 1. systemVersion	fictional-v1
observations 1. on	October 3, 2026
observations 1. actual	FICTIONAL authorized
observations 1. reportedOutcome	Passed
observations 1. reviewer	Fictional qualified reviewer
observations 1. rationale	FICTIONAL supplied observation
access 1. reference	ACCESS1
access 1. sourceIds	S1
access 1. identity	PERSON1
access 1. role	Fictional reviewer
access 1. authorized	Yes

Field	Value
access 1. approvedBy	Fictional qualified reviewer
access 1. approvedOn	October 2, 2026
auditEvents 1. reference	AUDIT1
auditEvents 1. sourceIds	S1
auditEvents 1. recordReference	RECORD1
auditEvents 1. recordVersion	fictional-v1
auditEvents 1. actor	PERSON1
auditEvents 1. on	October 3, 2026
auditEvents 1. event	Fictional review record
auditEvents 1. priorSha256	
auditEvents 1. newSha256	09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609
signatures 1. reference	SIGN1
signatures 1. sourceIds	S1
signatures 1. recordReference	RECORD1
signatures 1. recordVersion	fictional-v1
signatures 1. recordSha256	09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609
signatures 1. signer	PERSON1
signatures 1. printedName	Fictional reviewer
signatures 1. on	October 3, 2026
signatures 1. meaning	Fictional review approval
signatures 1. sourceKind	Customer record
signatures 1. authenticationReference	Fictional source authentication reference. Not application-authenticated.

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
Food and Drug Administration: Part 11 Electronic Records and Electronic Signatures. Scope and Application	FDA's 2003 nonbinding guidance distinguishes predicate-rule scope and limited enforcement discretion from Part 11 requirements that remain in effect. It supports access, audit-trail and signature-control evidence preparation. Historical obsolete predicate citations are not applied automatically. Qualified current scope decisions remain necessary; customer records do not become authenticated signatures.	October 9, 2026	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application