

COMPLIANCE WORKING RECORD

Medical device post-market data organizer

FICTIONAL evidence sample. Requires tailoring.

Document control

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

Document control and frozen case

Organize source-linked exact device/version events, customer follow-up dates and qualified MDR, safety signal, corrective-action and recall review records.

Field	Value
Case reference	FICTIONAL-CASE
Organization	Fictional Example Company
Subject	FICTIONAL named workflow preparation
Responsible reviewer	Fictional qualified reviewer
Preparation date	October 9, 2026

Field	Value
Scope	FICTIONAL selected records only. Requires tailoring and current qualified scope review.
Customer policy	POLICY1
Customer policy version	fictional-v1
Declared approver	Fictional qualified reviewer
Declared approval date	October 9, 2026
Decision boundary	No substantive decision or external filing made.

Named method and supported scope

Match exact device/version, selected reporting period and event kind. Calculate only approved customer follow-up intervals, distinguish open/late/timely closure, and require the four separate qualified human decision records. Retain original event descriptions and unresolved chronology.

No clinical signal detection, FDA reportability or recall finding, universal statutory interval, device clearance or MDR submission. Up to 100 records per table within 100,000 UTF-8 bytes for the complete input, 300,000 bytes for the complete result and 500,000 bytes for the workspace. Up to 20 original files, 10,000,000 bytes per original and 25,000,000 combined original bytes. Aggregate capacity

rejects rather than truncates. Originals stay in this browser unless the customer explicitly authorizes paid cloud saving.

Customer originals, observations, approvals and applicability remain source-attributed declarations. Hashes establish retained byte identity only.

No forced-labor or deforestation clearance, identity or tax decision, clinical determination, certification, regulator filing, recipient message or external submission occurs.

Complete accepted records and exact original bytes remain recoverable. Restore confers no fresh payment, consent, source authentication or approval authority.

Complete result counts

Measure	Value
Post-market events	1
Overdue customer follow-up rules	0

1. Original evidence source (S1)

State. Customer verification linked

Customer-declared source identity and verification. Byte hashes establish retained identity, not factual authentication.

Field	Value
id	S1
fileId	F1
locator	FICTIONAL original case source
sourceDate	October 1, 2026
custodian	Fictional customer custodian
description	FICTIONAL exact customer-approved case records
verification	Customer verified
verifiedBy	Fictional qualified reviewer
verifiedOn	October 9, 2026
Exact evidence source references	S1

2. Original byte manifest (F1)

State. Indexed

Complete attachment export requires the exact retained original bytes.

Field	Value
id	F1
name	fictional-original-case.json
contentType	application/json
bytes	4437
sha256	2f2c7587722f274d0b540eb69930ea0156d9bda6563a933300560bde57308e80
Exact evidence source references	S1

3. Frozen customer policy (POLICY1)

State. Documented

Exact approved customer scope. Legal applicability and substantive conclusions remain human decisions.

Field	Value
reference	POLICY1
version	fictional-v1
approvedBy	Fictional qualified reviewer
approvedOn	October 9, 2026
sourceIds	["S1"]
Exact evidence source references	S1

4. Customer follow-up interval (EVENT1/RULE1)

State. Timely customer closure recorded

Customer-approved 10-day interval from received date. This is not an inferred FDA statutory reporting deadline.

Field	Value
dueOn	September 30, 2026
followUps	[{"reference":"FOLLOW1","sourceIds":["S1"],"itemReference":"EVENT1","ruleReference":"RULE1","on":"2026-09-25","action":"FICTIONAL recorded follow-up","outcome":"FICTIONAL review completed","status":"Closed"}]
rule	{"reference":"RULE1","sourceIds":["S1"],"eventKind":"Fictional complaint","requiredFollowUpDays":10,"trigger":"Every event","rationale":"FICTIONAL customer interval. No FDA statutory deadline inferred.","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-09"}
Exact evidence source references	S1

5. Exact post-market event and human decisions (EVENT1)

State. Customer review records linked

Customer follow-ups and qualified decisions assembled. The tool does not detect a clinical signal, determine reportability, clear a device or submit an MDR.

Field	Value
reference	EVENT1
sourceIds	["S1"]
deviceReference	DEVICE1
deviceVersion	fictional-v1
lot	FICTIONAL-LOT
eventKind	Fictional complaint
receivedOn	September 20, 2026
eventOn	September 19, 2026
description	FICTIONAL supplied complaint fact. No actual patient data.
selectedRuleIds	["RULE1"]
patientOutcome	FICTIONAL customer-reported outcome
followUps	[{"reference":"FOLLOW1","sourceIds":["S1"],"itemReference":"EVENT1","ruleReference":"RULE1","on":"2026-09-25","action":"FICTIONAL recorded follow-up","outcome":"FICTIONAL review completed","status":"Closed"}]
decisions	[{"reference":"DECISION1","sourceIds":["S1"],"itemReference":"EVENT1","kind":"MDR reportability","position":"Accepted","rationale":"FICTIONAL qualified human decision record. No clinical or FDA conclusion inferred.","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-09"}, {"reference":"DECISION2","sourceIds":["S1"],"itemReference":"EVENT1","kind":"Safety signal","position":"Accepted"}]

Field	Value
	, "rationale": "FICTIONAL qualified human decision record. No clinical or FDA conclusion inferred.", "approvedBy": "Fictional qualified reviewer", "approvedOn": "2026-10-09"}, {"reference": "DECISION3", "sourceIds": ["S1"], "itemReference": "EVENT1", "kind": "Corrective action", "position": "Accepted", "rationale": "FICTIONAL qualified human decision record. No clinical or FDA conclusion inferred.", "approvedBy": "Fi
	ctional qualified reviewer", "approvedOn": "2026-10-09"}, {"reference": "DECISION4", "sourceIds": ["S1"], "itemReference": "EVENT1", "kind": "Recall review", "position": "Accepted", "rationale": "FICTIONAL qualified human decision record. No clinical or FDA conclusion inferred.", "approvedBy": "Fictional qualified reviewer", "approvedOn": "2026-10-09"}]
Exact evidence source references	S1

Complete accepted task inputs

The following exact accepted fields preserve every supplied task record, including orphan records and contradictions. Customer annotations remain attributed. Supported workbook and W-9 fields were extracted locally from the exact pinned original. Extraction establishes field identity, not factual authentication.

Field	Value
deviceReference	DEVICE1
deviceVersion	fictional-v1
periodStart	September 1, 2026
periodEnd	September 30, 2026
rules 1. reference	RULE1
rules 1. sourceIds	["S1"]
rules 1. eventKind	Fictional complaint
rules 1. requiredFollowUpDays	10
rules 1. trigger	Every event
rules 1. rationale	FICTIONAL customer interval. No FDA statutory deadline inferred.

Field	Value
rules 1. approvedBy	Fictional qualified reviewer
rules 1. approvedOn	October 9, 2026
events 1. reference	EVENT1
events 1. sourceIds	["S1"]
events 1. deviceReference	DEVICE1
events 1. deviceVersion	fictional-v1
events 1. lot	FICTIONAL-LOT
events 1. eventKind	Fictional complaint
events 1. receivedOn	September 20, 2026
events 1. eventOn	September 19, 2026
events 1. description	FICTIONAL supplied complaint fact. No actual patient data.
events 1. selectedRuleIds	["RULE1"]
events 1. patientOutcome	FICTIONAL customer-reported outcome
followUps 1. reference	FOLLOW1
followUps 1. sourceIds	["S1"]
followUps 1. itemReference	EVENT1
followUps 1. ruleReference	RULE1
followUps 1. on	September 25, 2026
followUps 1. action	FICTIONAL recorded follow-up
followUps 1. outcome	FICTIONAL review completed
followUps 1. status	Closed
decisions 1. reference	DECISION1
decisions 1. sourceIds	["S1"]

Field	Value
decisions 1. itemReference	EVENT1
decisions 1. kind	MDR reportability
decisions 1. position	Accepted
decisions 1. rationale	FICTIONAL qualified human decision record. No clinical or FDA conclusion inferred.
decisions 1. approvedBy	Fictional qualified reviewer
decisions 1. approvedOn	October 9, 2026
decisions 2. reference	DECISION2
decisions 2. sourceIds	["S1"]
decisions 2. itemReference	EVENT1
decisions 2. kind	Safety signal
decisions 2. position	Accepted
decisions 2. rationale	FICTIONAL qualified human decision record. No clinical or FDA conclusion inferred.
decisions 2. approvedBy	Fictional qualified reviewer
decisions 2. approvedOn	October 9, 2026
decisions 3. reference	DECISION3
decisions 3. sourceIds	["S1"]
decisions 3. itemReference	EVENT1
decisions 3. kind	Corrective action
decisions 3. position	Accepted
decisions 3. rationale	FICTIONAL qualified human decision record. No clinical or FDA conclusion inferred.
decisions 3. approvedBy	Fictional qualified reviewer
decisions 3. approvedOn	October 9, 2026
decisions 4. reference	DECISION4

Field	Value
decisions 4. sourceIds	["S1"]
decisions 4. itemReference	EVENT1
decisions 4. kind	Recall review
decisions 4. position	Accepted
decisions 4. rationale	FICTIONAL qualified human decision record. No clinical or FDA conclusion inferred.
decisions 4. approvedBy	Fictional qualified reviewer
decisions 4. approvedOn	October 9, 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
Food and Drug Administration: Medical Device Reporting. How to Report Medical Device Problems	FDA explains MDR reporting and distinguishes manufacturer, importer and user-facility duties. This tool organizes exact device/version events and qualified customer decisions. Follow-up deadlines come only from approved customer intervals. It does not detect clinical signals, determine reportability or recall necessity, infer universal FDA deadlines or submit an MDR.	October 9, 2026	https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems