

COMPLIANCE WORKING RECORD

Medical device QMS evidence assembler

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 current customer-selected QMSR requirements, controlled records, management/audit reviews and corrective actions for qualified review.

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 exact current QMS versions to selected requirements and source-hashed controlled records. Check required management, internal and supplier reviews, dated closure evidence and overdue actions. Flag retired QS citations for current mapping.

Current FDA QMSR baseline only. Exact ISO requirements come from customer-authorized sources. No full licensed checklist, certification, inspection or system-release authority. 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 QMS coverage	0
Overdue unresolved QMS actions	0

Complete preparation draft

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

Medical-device QMS evidence assembly. No certification, inspection or release authority created.

Device. DEVICE1

Frozen current QMS version. fictional-v1

Baseline. FDA QMSR effective 2026-02-02

Every exact expert-selected instrument requirement. [{"reference":"REQ1","sourceIds":["S1"],"instrument":"FICTIONAL customer-authorized current QMSR requirement","version":"fictional-v1","provision":"FICTIONAL selected current provision","exactRequirement":"FICTIONAL exact controlled-record requirement","selection":"Applicable","selectionRationale":"FICTIONAL qualified applicability rationale","re

cordIds":["RECORD1"],"reviewIds":["REVIEW1"],"approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-02"}]

Every controlled record. [{"reference":"RECORD1","sourceIds":["S1"],"version":"fictional-v1","requirementReference":"REQ1","qmsVersion":"fictional-v1","kind":"Fictional controlled record","on":"2026-10-03","status":"Current","owner":"Fictional record owner","sha256":"09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609"}]

Every management, internal and supplier audit review. [{"reference":"REVIEW1","sourceIds":["S1"],"requirementReference":"REQ1","qmsVersion":"fictional-v1","kind":"Management review","on":"2026-10-03","position":"Approved","rationale":"FICTIONAL qualified management review","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-04"}]

Every corrective action and closure support. [{"reference":"ACTION1","sourceIds":["S1"],"requirementReference":"REQ1","reviewReference":"REVIEW1","owner":"Fictional action owner","dueOn":"2026-10-08","status":"Closed","closedOn":"2026-10-04","closureEvidenceIds":["S1"],"closureRationale":"FICTIONAL controlled closure evidence","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

Field	Value
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

Field	Value
version	fictional-v1
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026
sourceIds	["S1"]
Exact evidence source references	S1

4. QMS corrective action (ACTION1)

State. Supported customer closure

Closure remains a qualified customer assertion supported by exact supplied records.

Field	Value
reference	ACTION1
sourceIds	["S1"]
requirementReference	REQ1
reviewReference	REVIEW1
owner	Fictional action owner
dueOn	October 8, 2026
status	Closed
closedOn	October 4, 2026
closureEvidenceIds	["S1"]
closureRationale	FICTIONAL controlled closure evidence
approvedBy	Fictional qualified reviewer
approvedOn	October 4, 2026
Days relative to due date	1
Exact evidence source references	S1

5. Current QMSR controlled evidence coverage (REQ1)

State. Customer current evidence assembled

The current FDA QMSR baseline is retained. ISO requirements must come from customer-authorized exact sources; no full ISO checklist or certification is invented.

Field	Value
reference	REQ1
sourceIds	["S1"]
instrument	FICTIONAL customer-authorized current QMSR requirement
version	fictional-v1
provision	FICTIONAL selected current provision
exactRequirement	FICTIONAL exact controlled-record requirement
selection	Applicable
selectionRationale	FICTIONAL qualified applicability rationale
recordIds	["RECORD1"]
reviewIds	["REVIEW1"]
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026
Every selected controlled record	[{"reference":"RECORD1","sourceIds":["S1"],"version":"fictional-v1","requirementReference":"REQ1","qmsVersion":"fictional-v1","kind":"Fictional controlled record","on":"2026-10-03","status":"Current","owner":"Fictional record owner","sha256":"09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609"}]
Every selected management/audit review	[{"reference":"REVIEW1","sourceIds":["S1"],"requirementReference":"REQ1","qmsVersion":"fictional-v1","kind":"Management review","on":"2026-10-03","position":"Approved","rationale":"FICTIONAL qualified management review","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-04"}]

Field	Value
Every corrective action	[{"reference":"ACTION1","sourceIds":["S1"],"requirementReference":"REQ1","reviewReference":"REVIEW1","owner":"Fictional action owner","dueOn":"2026-10-08","status":"Closed","closedOn":"2026-10-04","closureEvidenceIds":["S1"],"closureRationale":"FICTIONAL controlled closure evidence","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-04"}]
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
deviceReference	DEVICE1
qmsVersion	fictional-v1
baseline	FDA QMSR effective 2026-02-02
requirements 1. reference	REQ1
requirements 1. sourceIds	S1
requirements 1. instrument	FICTIONAL customer-authorized current QMSR requirement
requirements 1. version	fictional-v1
requirements 1. provision	FICTIONAL selected current provision
requirements 1. exactRequirement	FICTIONAL exact controlled-record requirement
requirements 1. selection	Applicable
requirements 1. selectionRationale	FICTIONAL qualified applicability rationale
requirements 1. recordIds	RECORD1
requirements 1. reviewIds	REVIEW1
requirements 1. approvedBy	Fictional qualified reviewer

Field	Value
requirements 1. approvedOn	October 2, 2026
records 1. reference	RECORD1
records 1. sourceIds	S1
records 1. version	fictional-v1
records 1. requirementReference	REQ1
records 1. qmsVersion	fictional-v1
records 1. kind	Fictional controlled record
records 1. on	October 3, 2026
records 1. status	Current
records 1. owner	Fictional record owner
records 1. sha256	09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609
reviews 1. reference	REVIEW1
reviews 1. sourceIds	S1
reviews 1. requirementReference	REQ1
reviews 1. qmsVersion	fictional-v1
reviews 1. kind	Management review
reviews 1. on	October 3, 2026
reviews 1. position	Approved
reviews 1. rationale	FICTIONAL qualified management review
reviews 1. approvedBy	Fictional qualified reviewer
reviews 1. approvedOn	October 4, 2026
actions 1. reference	ACTION1
actions 1. sourceIds	S1

Field	Value
actions 1. requirementReference	REQ1
actions 1. reviewReference	REVIEW1
actions 1. owner	Fictional action owner
actions 1. dueOn	October 8, 2026
actions 1. status	Closed
actions 1. closedOn	October 4, 2026
actions 1. closureEvidenceIds	S1
actions 1. closureRationale	FICTIONAL controlled closure evidence
actions 1. approvedBy	Fictional qualified reviewer
actions 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
Food and Drug Administration: Quality Management System Regulation. Effective February 2, 2026	FDA confirms QMSR became effective February 2, 2026 and incorporates ISO 13485:2016 by reference. The former QSIT inspection process was replaced. Exact customer-authorized requirements and current controlled records remain necessary. This preparation method neither reproduces a full licensed ISO checklist nor certifies compliance or creates the former audit-record exemption.	October 9, 2026	https://www.fda.gov/medical-devices/post-market-requirements-devices/quality-management-system-regulation-qmsr