ClinicOps Regulatory Information Integrity Review

Specimen discrepancy register - v1.5

Refined replacement for the earlier v1.4 specimen. This synthetic example shows the work-product structure used to reconcile regulatory information across client-approved controlled sources and declared downstream surfaces.

SYNTHETIC SPECIMEN - invented device names, values and evidence. Not a client report, compliance determination, legal opinion, safety assessment or release authorization.

Case	Aster Vascular Platform - synthetic
Review	Regulatory information integrity + change propagation
Evidence	2 controlled sources + 5 declared downstream surfaces
Findings	9 synthetic findings across 12 checks
Decision owner	Client RA/QA retains authoritative-source and release decisions

What this specimen proves

The structure of the ClinicOps review output: source traceability, discrepancy logic, unresolved-authority handling, change-propagation checks, corrective-action routing and explicit RA/QA decision points.

What it does not prove

Market adoption, regulatory compliance, product safety, or effectiveness in a real manufacturer environment. Those require real scoped work and qualified human review.

12 checks in this specimen

1. Source authority/status	2. Device/trade name
3. Basic UDI-DI consistency	4. Manufacturer name/address
5. Intended purpose	6. Indications/contraindications
7. Sterile/single-use status	8. Storage/handling
9. Model/catalogue IDs	10. IFU/label revision linkage
11. SS(C)P version/publication linkage	12. Declared change propagation

Severity is operational triage only: S1 Hold, S2 High, S3 Medium, S4 Low. It is not a regulatory, legal, clinical or safety classification.

Specimen finding register

Every finding preserves the observed evidence, state, proposed action route and the need for human disposition.

F-001	Basic UDI-DI	S1 Hold	AUTHORITATIVE SOURCE UNRESOLVED
Reference	Controlled source A: BUDI-ASTER-001		
Observed	UDI extract + controlled source B: BUDI-ASTER-002		
Route	RA/QA must designate the controlling source; ClinicOps does not choose.		
Owner	Client RA/QA - explicit disposition required before closure.		

F-002	Intended purpose	S2 High	CHANGE NOT FULLY PROPAGATED
Reference	Approved IFU v6.0 contains expanded intended-purpose wording		
Observed	SS(C)P v5.2 retains the earlier wording		
Route	RA/QA confirms whether SS(C)P update is in scope, then routes correction.		
Owner	Client RA/QA - explicit disposition required before closure.		

F-003	Contraindication	S2 High	MISSING DOWNSTREAM VALUE
Reference	Controlled statement includes nickel hypersensitivity contraindication		
Observed	Danish IFU excerpt does not contain it		
Route	Confirm applicable controlled wording and correct through document control.		
Owner	Client RA/QA - explicit disposition required before closure.		

F-004	Storage condition	S2 High	CONFIRMED DISCREPANCY
Reference	Label master: Store 5-30 C		
Observed	Released IFU: Store 5-25 C		
Route	Establish authoritative condition and reconcile affected surfaces.		
Owner	Client RA/QA - explicit disposition required before closure.		

F-005	Manufacturer address	S3 Medium	CHANGE NOT FULLY PROPAGATED
Reference	Approved change: 22 Meridian Park, Dublin 18		
Observed	Label artwork retains 8 Meridian Park		
Route	Correct label artwork after RA/QA confirmation.		
Owner	Client RA/QA - explicit disposition required before closure.		

Specimen finding register - continued

F-006	Trade name	S3 Medium	CONFIRMED DISCREPANCY
Reference	Product master: AsterFlex Peripheral Stent System		
Observed	EUDAMED extract: Aster Flex Peripheral Stent		
Route	Confirm approved trade name and reconcile the downstream record.		
Owner	Client RA/QA - explicit disposition required before closure.		

F-007	Sterile status	S3 Medium	CONFIRMED DISCREPANCY
Reference	Controlled master: Sterile - EO		
Observed	Distributor sheet: Non-sterile		
Route	Determine whether distributor material is controlled/remediable, then route correction.		
Owner	Client RA/QA - explicit disposition required before closure.		

F-008	SS(C)P version	S4 Low	VERSION-LINK MISMATCH
Reference	Publication index: SSCP v4.2 approved		
Observed	Public-link register: SSCP v4.1		
Route	Verify publication route and replace stale reference if required.		
Owner	Client RA/QA - explicit disposition required before closure.		

F-009	Catalogue ID	S4 Low	IDENTIFIER FORMAT DRIFT
Reference	Controlled master: AFS-080-40		
Observed	IFU table: AFS08040		
Route	Confirm permitted format and normalize the mapping rule.		
Owner	Client RA/QA - explicit disposition required before closure.		

Change propagation and closure

The review asks whether an approved fact propagated to every downstream surface that the client explicitly put in scope. A mismatch is a reconciliation finding, not a compliance conclusion.

Approved fact/event	Controlled	RIM	EUDAMED	IFU	SS(C)P	Label	Result
Intended-purpose update	PASS	PASS	PASS	PASS	OLD	PASS	HOLD
Manufacturer address change	PASS	PASS	PASS	PASS	N/A	OLD	HOLD
Storage baseline	PASS	PASS	PASS	DIFF	N/A	PASS	REVIEW

Example closure record

Finding	Reviewer disposition	Closure evidence	Status
F-001	Authoritative source not yet designated	Decision record pending	OPEN
F-002	SS(C)P update required within approved change	Revised controlled SS(C)P + publication evidence	OPEN
F-005	Label correction approved	Approved artwork revision + change record	VERIFY
F-009	Formatting normalization accepted	Mapping rule + reconciled output	CLOSED

What a real review delivers

Evidence population: bounded client-approved sources and downstream surfaces. **Discrepancy register:** observed and control values with evidence. **Unresolved-authority register:** conflicts requiring RA/QA decision. **Change-propagation map:** expected surfaces and open gaps. **Human-review record:** reviewer dispositions and review time. **Integrity verification:** hash-bound confirmation that the delivered bundle matches the reviewed package.

Release boundary: human approval can clear the exact ClinicOps work product for delivery. It never authorizes release of a device, controlled document, label, IFU, SS(C)P or regulatory submission.

Test the same structure on one real workflow
Start with one device family or Basic UDI-DI group, 1-3 controlled sources, 2-6 downstream surfaces, and one named qualified reviewer.
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