**PRD-42 — Pharma — DSCSA Serialization & Verification**

**Intent**

Achieve DSCSA compliance for prescription drug products via serialization, verification, transaction documentation, and suspect/illegitimate product handling—without storing unnecessary PHI.

**Preconditions**

• Products flagged as DSCSA-scope; serial/lot tracking (PRD-17).

• Barcode/label templates (GS1 2D/linear); partner roles (manufacturer, wholesaler, dispenser).

• Document vault for T3 (TI/TH/TS) artifacts; verification routing endpoints (where applicable).

**Steps**

• Serialization: generate/ingest SGTIN/SSCC per packaging level; bind serials to lots and ProductVersion; store generation receipts.

• Labeling: render GS1-compliant labels with required application identifiers; preview and lock against version drift.

• T3 Documentation: capture Transaction Information/History/Statement for each transfer; sign and store T3 Receipts with partner linkage.

• Verification Flow: on suspect/verification request, query appropriate repositories/partners; log request/response with hash receipts.

• Returns/Re-Dispense: validate returned product via verification and condition checks; accept/reject with WHY and audit trail.

• Suspect/Illegitimate Handling: create case, quarantine stock, notify partners/regulators as policy dictates; attach evidence and case outcome.

• Gate Hooks: shipments require valid serial status and T3 availability; holds when serial state is decommissioned/unknown or T3 missing.

• Reporting & Reconciliation: dashboards for serial states, exceptions, verification SLAs; periodic reconciliation jobs with partners.

**Edge cases**

• Mixed packs with different serial hierarchies → enforce parent-child relations before shipment.

• Repository outages → queue verifications with fallback policy; never ship without meeting minimum verification requirements.

**Done when**

• Serials are trackable through packaging levels, verification requests are auditable, T3 documents are present for transfers, and holds prevent non-compliant movements.