

Clinical-to-Commercial Test Run Playbook

For clinical-stage biopharmaceutical companies planning their first commercial lots



Executive Summary

Phase 3 compresses timelines and magnifies serialization risk. You are simultaneously finalizing labeling, and meeting country/market requirements (e.g., DSCSA in the U.S., EU FMD).

This playbook lays out a pragmatic path to readiness with clear entry/exit criteria, a full-fidelity test run, and cutover controls that won't jeopardize your commercial launch.

Outcomes

- Serialization design decisions locked
- Partners onboarded and exchanging EPCIS
- Artwork controls aligned with serialized packaging realities
- Validation complete
- Test Run executed with realistic master data, packaging flows, and exception scenarios
- Go-live plan



Roles & RACI

| | Responsibilities | | |
|----------------------------------|--|--|--|
| MAH | Owns serialization strategy, master data, compliance posture | | |
| QA/CSV | Validation, deviation management, release/recall readiness | | |
| Serialization Lead | Data model, EPCIS choreography, partner onboarding | | |
| Packaging Ops (internal/CMO/CPO) | Line readiness, aggregation/rework | | |
| Regulatory/Labeling | Artwork freeze, market-specifics | | |
| Supply Chain/Planning | Safety stock, cutover calendar | | |
| 3PL/Distribution | 3PL/Distribution Verification, returns, DSCSA/FMD messaging | | |
| IT/Security | Environments, access, audit trail | | |



Critical Path



Readiness

- **Gap assess:** lines, devices, site servers (L3), repository (L4), 3PL, VRS/returns.
- **Decide ownership boundaries:** who issues SGTINs, who hosts L4, who sends EPCIS.
- **Draft Data Contract:** attributes, event types, file frequencies, error codes.
- **Build Master Data Pack:** GTINs/NTINs, packaging hierarchies, SSCC policy, locations (GLNs), partners.



Artwork

- Freeze label data elements, tamper-evidence marks, DMs (2D/linear), human-readables.
- **Partner mapping:** CMO/CPO/3PL endpoints, certificates, protocols, message types.
- **Create Connectivity Plan** with sequencing (by product/CMO) and mock files.



Critical Path



Line & Data Trials

- Line run on empty/cheap components: confirm code quality, vision thresholds, reject logic.
- **Aggregation & rework flows:** palletization and SSCC issuance.
- Generate controlled test SN pools and test batches for the coming Test Run.



Connectivity/EPCIS

- Exchange sample EPCIS: commissioning, packing, shipping, receiving; validate against data contract.
- Stand up exception queues, error codes, and retry/escalation rules.



Critical Path



Validation & Training

- **Risk-based CSV:** URS/DS, IQ/OQ/PQ for L3/L4 and key interfaces.
- **SOPs:** serial number management, aggregation/rework, exception handling, returns/verification.
- **Conduct table-top exercises:** mock recall, suspect/verification, label change.



Full Test Run & Cutover

- Execute the Test Run (details on next pages).
- Go/No-Go with entry/exit criteria: finalize stabilization plan.

Purpose: Prove that your end-to-end serialization ecosystem can produce, move, verify, and (if needed) rework serialized product without compromising trial integrity or market compliance.



Scope & Environments

- End-to-end path: CMO/CPO line → MAH L4 →
 3PL/DC → (optional) mock wholesaler/dispense
 node.
- **Systems in scope:** L3 (site), L4 (repo/network), WMS/TMS, label/vision, VRS/verification, QMS (deviations), ERP (lot release).
- **Data sets:** at least 2 GTINs and 2 batches with realistic expiry, distinct SN pools, known bad data for negative tests.



Entry Criteria

- **Approved URS/DS:** IQ/OQ complete for systems in scope.
- Data contract signed with each partner: certificates and creds provisioned.
- Artwork frozen: master data loaded and reconciled, SOP drafts available.





Shipping Validation

- **Objective:** Prove the finished-goods pack + shipper protect product quality across worst-case lanes and seasons before PPQ/commercial launch.
- **Standards & protocols:** Use ASTM D4169 (full distribution simulation), ASTM D4332 (environmental conditioning), ASTM D4728 (random vibration) and/or ISTA 3A/2A (parcel simulations) as appropriate to dosage form, packout, and lanes.
- **Tests (examples):** free-fall/drop; random vibration; compression; winter profile (low-temp exposure); high-temp/humidity; altitude/pressure (air); thermal cycling; label adhesion/legibility; code robustness (read rates posttest).
- **Evidence:** lab reports (protocols, results, deviations), data logger traces, pictures, post-test code verification (1D/2D grade), disposition & CAPA if failures.





Success Metrics (Examples)

- **Data integrity:** 100% parent/child consistency; 0 orphan children; all EPCIS valid against schema & contract.
- Performance: EPCIS end-to-end latency ≤ 15 min (target) partner-to-partner.
- **Quality:** Deviations closed or CAPA initiated within 5 business days; zero open criticals.
- **Traceability:** Recall drill completed with correct counts/locations within SLA.
- Clinical safety: No unblinding events; access controls verified.



Evidence Pack (What to Save)

- Test plan & scripts; signed execution records.
- EPCIS samples (good & bad), acknowledgements, and message logs.
- Vision images for rejects; line audit trail; rework records.
- Verification/returns evidence; recall drill output; deviation/CAPA.
- Training sign-in, SOP read-and-sign, and role competency checks.





Exit Criteria (Ship-Ready)

- All scenarios executed; defects triaged; criticals closed; mediums have workarounds.
- Partners confirm contract conformance; round-trip acknowledgements pass.
- Go/No-Go review signed by QA, Supply Chain, Serialization Lead, and CMO/3PL reps.



| Scenarios (Minimum Set) | Objective | Owner | Pass Criteria | Evidence Saved |
|---|--|--|--|--|
| Commission & Pack | Commission ~5,000 units → bundle → case → pallet; exchange commissioning/aggregation EPCIS; receive at 3PL; verify hierarchy | Packaging Ops (CMO/CPO) Serialization Lead 3PL | 100% parent/child consistency; 0 orphan children; EPCIS valid to schema/contract; round-trip acks; partner-to-partner EPCIS latency ≤ 15 min | EPCIS samples & acks; 3PL receipt logs; line audit trail; vision images of codes |
| Partial Pallet & Re-aggregation | Break a case; re-aggregate remaining units; update events and confirm parent/child integrity | Packaging Ops Serialization Lead | Post-re-agg hierarchy correct; no orphans; all events accepted/acked | EPCIS re-agg messages; hierarchy report; rework records |
| Rework/Relabel | De-aggregate a case; relabel 20 units for cosmetic defect; re- commission + re-aggregate with intact audit trail | Packaging Ops QA/CSV | New SGTINs commissioned; prior SGTINs correctly voided (if applicable); audit trail shows de-agg → relabel → recommission; code grades at/above target | Rework records; vision images; EPCIS event se (de-agg/void/commission/pack) |
| Short Ship / Over Ship | Ship 99/100 cases; catch discrepancy at receiving; send correction/void events; align inventory | 3PL/Distribution Supply Chain Serialization Lead | Discrepancy flagged at receiving; correction/void accepted; inventory counts match ship/receive | Receiving logs; EPCIS correction/void + acks; inventory adjustment record |
| Returns & Verification | Initiate a sample return; verify pack SGTINs via VRS (or EU EMVS/NMVS); disposition captured | 3PL/Distribution QA/CSV | Verification returns expected status; disposition recorded; no unblinding | VRS verification evidence (screens or logs); return RMA/disposition; EPCIS status updates |
| Suspect Product | Mark one SGTIN "suspect"; propagate status; block verification; document investigation | QA/CSV Serialization Lead | Status change visible in L4/partner; verification blocked; deviation opened; CAPA started if needed | Status-change logs; VRS response; deviation/CAPA record |
| Data Failure / Retry | Inject EPCIS with a schema error; confirm rejection, alerting, fix, and resubmission | Serialization Lead IT/Security | Invalid message rejected; alert fired; corrected message accepted; round-trip acks | Bad EPCIS sample + error log; alert evidence; corrected EPCIS + acks |
| Blinded Kit Protection | Ensure events/messages avoid exposing treatment arm; confirm masked data in reports/logs | Serialization Lead Regulatory/Labeling IT/Security | No unblinding events; access controls verified; masked fields confirmed | Sample/redacted payloads; access audit logs |
| Mock Recall | Select one lot; trace commissioned → shipped → received hierarchy; produce recall list | QA/CSV ■ Supply Chain | Recall drill output produced within SLA (< 2 hours) with correct counts/locations | Recall list/report; traceability audit trail |
| Distribution Qualification & Shipping Validation | Run ASTM/ISTA distribution simulations on final artwork/packout with production-like codes; confirm label & shipper performance | Packaging Ops ■ QA/CSV | Protocols executed; label integrity maintained; barcode/Datamatrix grades ≥ target; shipper thermal performance meets worst-case seasonal profiles | Lab protocols & reports; data-logger traces; photos; post-test code verification; CAPA if failures |

YOU DESERVE TO STAY FOCUSED ON YOUR LAUNCH,

NOT ON VENDOR COORDINATION...

What Phase 3 teams actually need:

- Fewer vendors to manage
- Scalable infrastructure
- Validation support

For minimal distractions from their launch priorities



VerifyBrand™ eliminates the multi-vendor coordination chaos

The True One-Stop Shop for Clinical Serialization

We deliver the platform, validation, integrations, compliance, and support - all in-house.

What you *don't* get:

X Consultant management

X Third-party coordination

X Multi-vendor blame games





They come for the software. They stay for the service.



Why Choose OPTEL

GLOBAL EXPERTISE, LOCAL SUPPORT



35+

YEARS OF EXPERTISE in traceability and vision systems



Presence in more than **30 COUNTRIES**

6,000+

SYSTEMS INSTALLED worldwide



24/7 international **TECH SUPPORT**

Want to stay focused?

Connect with our traceability experts to get pricing and a personalized demo.

Connect with us online

