

Most Common Serialization Mistakes

Session at a glance

Most serialization failures in mature setups are not technical: they stem from undocumented procedures, unclear ownership and misaligned master data between partners.

Webinar' s Agenda

- Packaging line and software mismatches
- EPCIS and partner data exchange
- EU alert management
- Ownership and responsibility
- Stress-testing the setup for change



1. Packaging line and software mismatches

The most frequent root cause of line issues is untrained personnel and undocumented procedures, not software.

Mismatches typically surface between what happens on the line and what reaches the enterprise system, especially at sites manufacturing for themselves and for third parties.

Assessment framework: four pillars supporting the business

- Data Visibility
- Partner Integration
- Contextualized Data
- Process Orchestration

Serialization levels referenced

L2 › L3 › L4 › L5

Common issues observed

Multi-vendor lines. Sites often run several line vendors (e.g. Antares, Seavision, Wipotec, Laetus) on a common L3. Integration challenges appear during the installation project, not in steady-state operation. Line-level problems reported by the audience were specific to the installed line software; compatibility risk rises when hardware and software come from different providers.

Level skipping is viable. One attendee connects L3 directly to L5 (Uzbekistan traceability portal). Others connect L2 directly to L4 with no site server. Acceptable if the setup is GMP-compliant and supports record-keeping and reconciliation. L4 earns its place when an organization works with multiple partners or CMOs.

Nubinno's recommendation: do not neglect documentation. Define procedures and responsibilities per team. Errors can always be fixed; missing know-how costs more than training.

2. EPCIS and partner data exchange

EPCIS was the audience's top problem area. Most go-live issues stem from partner software limitations, and risk grows with the number of trading partners.

Definition. EPCIS is a GS1 transaction standard; every event answers what, when, where and why. In practice it is one medium for inter-company serialization data exchange; the same issues arise with other formats.

Where issues occur

1

Onboarding

defects are caught in testing cycles (feedback, retest, revised test files) and are not treated as production issues.

2

Live operation

with roughly one batch a day per partner, issues can occur daily, mostly due to partner software limitations.

3

Scale

more partners means higher probability of failure and a stronger case for an L4 system.

Case studies

Partner onboarding checklist

- ✓ Quality agreement signed, defining data-exchange expectations on both sides
- ✓ Master data exchanged and aligned on all sides
- ✓ Expected EPCIS event types agreed (including aggregation, if the CMO aggregates)
- ✓ Negative testing performed to confirm correct system behaviour on invalid input
- ✓ Troubleshooting responsibilities defined, including CAPA documentation for partner-caused errors
- ✓ Clear ownership of the connection

Audience Q&A

3. EU alert management

EU alerts are mostly caused by end users and are straightforward to close; MAHs can reduce volumes by analysing alert patterns and adjusting serial number formats.

Context. EU alerts are an anti-falsification measure unique to the EU; other markets use their own exception-handling procedures. According to the speakers, the EU stabilization period ended in 2025 and most markets now handle alerts routinely.

Most common causes



Reduction levers for MAHs (as serial number source)

- Analyse alerts proactively to identify recurring patterns.
- Remove error-prone characters from serial number pools.
- Switch to numeric-only serials. This also happens during divestments, where the buyer keeps serial length but changes format, or where software cannot handle alphanumerics.

4. Ownership and responsibility

Concentrating serialization in one or two people is a business continuity risk; every organization should maintain a serialization responsibility matrix.

Ownership trend. Ownership has shifted from IT towards business and Quality. The poll confirmed it: Quality first, then Supply Chain and Operations, IT lowest. In smaller companies IT often wears several hats and stays closer to serialization; in larger ones IT focuses on infrastructure. Supply Chain involvement varies, from full ownership of partner relationships to warehouse-only.

The single-owner risk

- Serialization is usually assigned to one or two people in Quality or Supply Chain, on top of their main role.
- The role spans technical, compliance and business-planning knowledge, which is too much for one person.
- Departure, sick leave, holiday or maternity leave leaves a gap that a successor cannot easily fill without documented processes.
- Nubinno reported multiple client cases of exactly this scenario.

Recommended team models



- Minimum coverage rule (L. Mbrasevich): at least 1.5 people per role, so that one can always cover for the other.



5. Stress-testing the setup for change

Most setups went live around 2018 and run stably until something changes; the test is what breaks first when it does.

Action checklist

1	Document day-to-day line and exception-handling procedures; train backup personnel
2	Monitor serial number pool levels against production volumes
3	Align master data across L3, L4 and all partners before launching new articles
4	Sign quality agreements covering serialization data exchange with every CMO and partner
5	Agree EPCIS event types and run negative testing during onboarding
6	Verify that EU Hub uploads trigger automatically; question any manual workaround
7	Analyse EU alert patterns and adjust serial number formats where needed
8	Build a serialization responsibility matrix with at least 1.5 people per role
9	Stress-test readiness for vendor, partner and market changes before they happen



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