

Pharma serialization audit



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Preparing for NCA and Customer Audits

In the pharmaceutical industry, serialization audits conducted by National Competent Authorities (NCAs) or customers can take various forms – from physical site visits to virtual meetings or postal audits through questionnaires.

Each format requires specific preparation but shares a common focus: demonstrating control, compliance, and traceability in serialization practices.

Key expectations from auditors include:

- Clear documentation of processes
- Well-maintained training records
- Access to SOPs and validation reports
- Role-based responsibilities clearly defined

Whether the audit is physical or virtual, companies must ensure:

- Availability of knowledgeable personnel
- Up-to-date documentation
- Internal alignment across serialization touchpoints (e.g., packaging, artwork, data systems)

Auditors often request training evidence related to system upgrades or procedural changes, highlighting the importance of continuous education and documentation.

Assessing Serialization Readiness Internally

Before facing external audits, companies should conduct internal assessments to measure their preparedness. This involves:

- Reviewing documentation (SOPs, URS, validation reports)
- Verifying system configurations align with documented processes
- Confirming data integrity protocols are in place
- Ensuring training records reflect actual operational procedures

An internal audit or readiness check helps:

- Identify documentation gaps
- Test system robustness
- Validate team roles and responsibilities

Using structured scoring systems or compliance metrics across people, systems, and data ensures a comprehensive evaluation.

Conducting Internal Serialization Audits

Internal serialization audits should simulate the structure and depth of official audits.

Key components include:

- Team preparation and role assignment
- Review of change management and impact assessments
- Mock audit scenarios (including system failure simulation if feasible)

Focus areas include:

- Evidence readiness
- Aligned documentation
- Clear organizational structure

A third-party like Nubino can facilitate these audits, providing scoring, recommendations, and even Total Cost of Ownership (TCO) analysis to help optimize resources.

Evaluating External Partners and Acquisition Targets

Serialization responsibilities often extend to external CMOs/CPOs. Evaluating their readiness is crucial, especially when:

- Selecting new partners
- Auditing vendors
- Considering acquisitions

Audit considerations should include:

- Contractual clarity on serialization duties
- Documentation from partners
- Alignment with compliance standards in target markets

Auditors may request evidence of how vendors are selected, evaluated, and managed – making vendor audits or postal questionnaires a critical part of due diligence.

Q&A Highlights and Takeaways

During the webinar, participants asked insightful questions. Here are the highlights:

Q: How can companies simulate module failures?

A: This requires controlled test environments and collaboration with IT or cybersecurity teams.

Q: Can tools be used for performance testing?

A: Typically restricted due to data security, but internal teams can create testing scripts and simulation scenarios.

Q: Is a dedicated serialization role required?

A: Yes. Each company must designate someone responsible for serialization oversight.

Q: How often should internal audits occur?

A: Ideally every 12–24 months, with periodic evaluations or readiness checks in between.