

Pharma serialization in Italy



CEO, Nubinno

SPEAKER:
JAROSŁAW RADZIKOWSKI

Agenda:

- **Key considerations** before starting serialization
- **Selecting the right vendor**
- **Integrating serialization seamlessly**
- **Managing your first serialized shipment**
- **Common pitfalls** in serialization
- **The road ahead:** emerging trends and the bright future of serialization



www.nubinno.com

Introduction

Serialization is no longer a future requirement—it's a present-day necessity for pharmaceutical manufacturers, Marketing Authorization Holders (MAHs), and Contract Manufacturing Organizations (CMOs). In Italy, where regulatory enforcement is active and closely aligned with EU Falsified Medicines Directive (FMD) standards, having a serialization strategy is critical not only for compliance, but also for maintaining supply chain integrity, commercial continuity, and patient safety.

This e-book provides a step-by-step guide to launching, integrating, and optimizing serialization activities in Italy. Whether you're just beginning the process or looking to fine-tune an existing program, the following chapters will help you avoid common pitfalls and design a future-ready serialization strategy.

02

www.nubinno.com

Key considerations before starting serialization

Before you select a vendor or start integrating systems, it's important to build internal alignment and readiness:

- **Regulatory Requirements:** understand both EU FMD and Italian AIFA mandates. Italian stakeholders must also interface with the national Medicines Verification System (NMVS)
- **Business Drivers:** serialization can open doors to traceability, anti-counterfeiting, and digital health initiatives
- **Team Formation:** involve stakeholders from QA, IT, Production, Regulatory, Supply Chain, and Business Operations
- **Gap Analysis:** evaluate current systems, packaging processes, and data flows. Identify gaps in infrastructure and documentation

03

www.nubinno.com

Selecting the right vendor

Choosing the right serialization partner is a make-or-break decision. There is no one-size-fits-all approach, and different vendors specialize in different levels of the serialization stack (L4 cloud, L5 line-level, ERP integration, etc.).

- **Criteria for Selection:**
 - Integration capability with existing systems
 - Regulatory experience in Italy and Europe
 - Validation and support services
 - Scalability for future markets and volume
- **Process:**
 - Run an RFX or RFP process with defined scoring metrics
 - Ask for references and conduct capability assessments
 - Clarify roles: Who is responsible for what (vendor, MAH, CMO)?

Vendor partnerships should extend beyond implementation. Choose a partner that can guide you through regulatory updates, exception handling, and alert management.

04

www.nubinno.com

Even the best-laid plans can falter without risk management. Avoid these frequent issues:

- **Underestimated Timeline:**
Serialization takes 6–12 months, not 6–8 weeks
- **Poor Master Data Management:**
Inaccuracies here create system-wide disruption
- **Lack of CMO Coordination:**
Misaligned processes between MAHs and CMOs result in failed batches
- **Insufficient Validation:**
Skipping PQ or not documenting workflows invites regulatory trouble.

www.nubinno.com

06

Common pitfalls in serialization projects

Conclusion

Serialization readiness in Italy is both a regulatory requirement and a strategic advantage. By planning early, selecting the right partners, integrating effectively, and preparing thoroughly for your first shipment, you can reduce risks and set a foundation for future growth.

Nubinno is here to support your serialization journey. From vendor selection to validation, from first shipment to long-term strategy, our team ensures you stay compliant and competitive.

— The Nubinno Team

Conclusion

You can reach us at: office@nubino.com