

Associate Director Serialization and Product Tracking (SPT) Operations

Job ID

REQ-10047572

Apr 23, 2025

Spain

Summary

The Associate Director for Serialization and Product Tracking Operations is responsible for leading the serialization onboarding process for external suppliers, as well as ensuring the implementation and operational stability and security of Track and Trace solutions.

About the Role

Role Responsibilities:

- Lead the serialization onboarding process for external suppliers such as CMOs. Perform the required assessment, preparation of user requirement specifications and the testing activities to ensure successful serialization data exchange.
- Provide guidance and direction on serialization & product tracking related activities
- Lead the development and implementation of an effective compliance program for Track and Trace markets and product safety, identifying potential compliance risks associated with business strategies, and establishing effective controls and compliance oversight related to those risks.
- Develop a compliance program foundation which includes oversight of a Track and Trace program structure and foundation, ensuring that all elements of an effective compliance program are in place and integrated into existing structures and processes where appropriate.
- Ensure a thorough understanding of the regulations (both what is required and what is recommended) is used to build the processes, systems, and controls to maintain compliance throughout the product supply chain
- Partner with external trading partners and internal stakeholders to help understand and resolve more complex matters such as tracing, verification, and suspect product investigations.
- Implement monitoring programs to ensure manufacturing site compliance and exception management.
- Lead and support Novartis serialization system implementation around SAP ATTP and SAP ICH system.
- Support Novartis internal manufacturing system and contract manufacturing system integration using ATTP, ECC and SAP ICH system.
- Design and deploy the serialization solution enhancements in ATTP, SAP ICH systems.

Role Requirements:

- Bachelor's degree in a technical field.
- Understanding of global regulations and Health Authorities expectations governing computerized systems (CSV, Part 11, etc.).
- Experience in the development, implementation and lifecycle management of computerized systems in

regulated environments.

- Experienced in the operational management of GxP solutions including the related technologies to support the operations..
- Supply Chain and Project Management experience.
- Pharmaceutical, Generics experience and SAP experience.
- Subject matter expertise in pharmaceutical product serialization, track and trace systems (SAP ATTP, ICH, EPCIS, GS1, etc.) and associated challenges and risks impacting the supply chain.
- Significant experience and familiarity with relevant regulatory requirements, including federal / state / international regulations, DSCSA requirements, verification of trading partners, etc.
- Strong problem-solving and communication skills to interact with senior leadership and regulatory agencies.
- Ability to drive organized, multi-function collaboration, including with non-SC part.

Benefits & Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: [Novartis Life Handbook](#)

Benefits in Spain include Company Pension plan; Life and Accidental Insurance; Meals; Allowance or Canteen in the office; Flexible working hours.

Commitment to Diversity & Inclusion:

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

This role is based in Barcelona, Spain. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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Division

Operations

Business Unit

Universal Hierarchy Node

Location

Spain

Site

Barcelona Gran Vía

Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.

Alternative Location 1

Ljubljana, Slovenia

Alternative Location 2
Prague, Czech Republic
Functional Area
Technology Transformation
Job Type
Full time
Employment Type
Regular
Shift Work
No
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