

Sr. Manager Serialization & Product tracking Operations

Job ID
REQ-10028849
nov 22, 2024
Espagne

Résumé

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Business Process Owner (BPO) for serialization systems

BPO for the Product Security features. SME for serialization requirements across all markets. Ensuring end-2-end process upgrade or creation for serialization / product tracking. Ensure Track and Trace regulatory compliance for upcoming markets as well as ongoing markets by working closely with the country organization, supply chain, sites and ESO (External Supplier Organization). Establish, manage Novartis Track and Trace processes with aim to achieve Novartis objectives. EMVO SPOC

About the Role

Major accountabilities:

- Provide guidance and direction on serialization & product tracking related activities
- Process and Supply Chain mapping from a serialization and product tracking perspective
- 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.
- Develop a staffing strategy to meet technical and project deployment priorities for Serialization.

- Lead the team responsible for implementing track & trace solutions for the regions

Minimum Requirements:

Work Experience:

- 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. .
- Experience in GxP qualification activities
- Participation in Industry association forums related to serialization
- 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

Languages :

- English.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world.

How can we achieve this?

With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

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Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
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Ljubljana, République de Slovénie
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Employment Type
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Shift Work
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