

Associate Director DDIT OPS SPT Process

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REQ-10068839
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Сводка

The Associate Director for Serialization and Product Tracking Process is responsible for defining and managing serialization/aggregation processes in impacted areas such as manufacturing, warehouse and supply chain in line with regulatory requirements and Novartis objectives.

About the Role

Major accountabilities:

- Own, define and map serialization and product tracking processes in manufacturing, warehouse and supply chain. Define standard global process and ensure alignment and implementation at local level (manufacturing sites, warehouses) as well as in global supply chain (e.g. third-party logistics, order management, etc)
- Ensure end-to-end process documentation in regard to serialization/aggregation is available and maintained updated on ADONIS as process master data repository.
- Identify opportunities for process optimization and drive initiatives to enhance process efficiency, effectiveness, and quality.
- Define optimum metrics and KPIs needed to measure process performance.
- Ensure the SPT documentation in QMS reflects updated requirements and processes and follows the simplification approach defined for QMS. Define new documents if needed and execute periodic review of documents.
- Lead identification of process automation opportunities and work on the implementation of the solutions / technologies.
- Provide guidance and direction on serialization & product tracking related activities
- Partner with external trading partners and internal stakeholders to help understand and resolve more complex matters such as tracing, verification, and suspect product investigations.
- 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.

Minimum 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.
- Experience in GxP qualification activities.
- 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.
- Ability to drive organized, multi-function collaboration, including with non-SC part.

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>

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.

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Дивизион
Operations
Business Unit
Information Technology
Место
Индия
Сайт
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Информационные технологии
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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List of links present in page

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