

# Associate Director DDIT OPS SPT Process

Job ID

REQ-10068839

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Индия

## 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.

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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

Technology Transformation

Job Type

Full time

Employment Type

Regular

Shift Work

No

Job ID

REQ-10068839

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