

Manufacturing Data System Expert

Job ID

REQ-10034396

Jan 07, 2025

India

Summary

Novartis operates multiple manufacturing sites globally to produce cutting-edge Cell and Gene Therapy products and Biologics (Large Molecules).

As a Discoverant Specialist, you will play a pivotal role in supporting the Discoverant System Business Owner within Novartis Technical Operations (NTO). Discoverant is a validated IT solution utilized across NTO for automated manufacturing data aggregation, advanced analysis, and comprehensive reporting.

In this role, you will act as the global Discoverant Super User, collaborating with IT teams, manufacturing sites, and the Discoverant Global Business Owner. Your responsibilities will include ensuring optimal system setup, seamless change implementations, and ongoing maintenance of the Discoverant platform across the Novartis network.

About the Role

Major Accountabilities

- Serve as the primary business-side representative for the implementation, lifecycle management, and ongoing evolution of the Discoverant system, ensuring effective collaboration with local users, IT, and system vendors under the guidance of the business owner.
- Coordinate Discoverant interfaces with integrated IT systems, including ERP (SAP), MES, LIMS, Data Historians, and patient scheduling tools (e.g., CellChain), leveraging cloud-based manufacturing and quality data storage solutions.
- Facilitate onboarding for new internal and external users, conduct training sessions, and promote knowledge sharing among end users.
- Develop and optimize data analytics components, including dashboards, control charts, automated reports, and advanced analytics, utilizing best practices and tools like Pipeline Pilot.
- Drive change control processes for the Discoverant system, integrating new parameters, products, and architectural updates, including respective interface modifications, while supporting local and global risk and impact assessments.
- Support data integration from new systems and parameters into Discoverant to meet manufacturing data trending and analysis needs, aligning data flow from source systems to Discoverant and advanced analytics platforms.
- Assess data quality, implement corrective actions, and propose improvements to ensure data accuracy and reliability.
- Manage manufacturing data provision for internal stakeholders outside the manufacturing group.
- Address and resolve Discoverant-related deviations, quality events, and associated actions.
- Act as a liaison between local Discoverant users, IT teams, and system vendors to ensure smooth operations and system enhancements.

- Author and maintain Discoverant-specific Standard Operating Procedures (SOPs) and Working Procedures (WPs).

Key Performance Indicators (Indicate how performance for this role will be measured)

- Quality / Accuracy / Right First Time
- Timeliness
- Deviations / Escalations

Job Dimensions (Number of staff reporting)

Indicate key facts and figures) Direct: 0

Financial responsibility (Budget, Cost, Sales, etc.)

Operational Budget: na

Impact on the Organization

- Contribute to increased level of automation in manufacturing
- Significant impact on ensuring competitive advantage in quality and costs by improving the relevant data and digital technology standards
- Contribute to Site Manufacturing financial / business goals.
- Minimize process-related rejected batches and write-offs.
- Maximize process robustness

Skills:

- Good Documentation Practice
- Effective communicator
- Strong cross functional collaboration
- Adaptability to Embrace Change
- Effective stakeholder engagement
- Manufacturing Process
- Knowledge Of GMP (Good Manufacturing Practices)
- Change Control
- Deviation management
- Corrective and preventive action (CAPA)
- Continual Improvement Process
- General HSE Knowledge
- Manufacturing (Production)

Ideal Background / Requirements for the role

Education (minimum):

University degree in Engineering, Computer Sciences, Technology (Chemical/Biology) or similar field

Languages

- Fluent in English and additional languages desirable (German, French, other)

Relevant Experiences

- 5 years of practical experience in the pharmaceutical industry, with expertise in manufacturing IT systems.
- Hands-on experience with Biovia's Discoverant and Pipeline Pilot tools.
- Knowledge of integrated IT systems such as ERP (SAP), MES, LIMS, OSI-PI, SQL, Oracle/MS SQL databases, and cloud-based data storage solutions.
- Comprehensive understanding of pharmaceutical cGMP, Computerized System Validation (CSV), and regulatory requirements.
- Familiarity with statistical tools and programming languages such as Minitab, JMP, Python, and R is a plus.
- Knowledge of data handling applied statistics, and Six Sigma methodologies.
- Proven ability to collaborate effectively with team members, site experts, and organizational leaders, with a capacity to influence without direct authority.
- Solid project management and presentation skills, with the ability to lead cross-functional initiatives.
- Excellent communication and interpersonal skills to foster collaboration and drive results.

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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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division

Operations

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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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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