GLIMS Developer, Global DQC CoE

Job ID
REQ-10027499
Oct 28, 2024
India

Resumen

-Responsible for managing quality aspects within area of responsibility and to ensure that the operational business is in compliance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements and the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures

About the Role

Job Purpose:

The Global Lab Information Management Systems Expert supports the efforts to develop and enhance data management systems managed by the Global DQC CoE and is responsible under the lead of the Global Lab Information Management Systems Lead for development, enhancement and maintenance of these systems to meet the needs of the organization and maximizes the value creation of the applications

Experience Required: Minimum 10 years of laboratory experience in a pharma industry.

Major Accountabilities:

- Act as the business system developer for the Lab Information Management Systems maintained globally by the DQC CoE: LabWare LIMS
- Identifies and anticipates site needs, determines what features should be implemented, and support prioritization of the backlog items.
- Supports establishment of release timelines, content of each release, oversee the application development stages and supports completion of each release in accordance with the approved plan.
- Performs configuration of new functionalities, conducts code review and supports business screening, PQ scripting and PQ execution.
- Supports continuous improvement in report templates, labels, folder templates, calculations and interfaces between the systems in scope
- Supports Business screening, PQ scripting and PQ execution.
- Provides required periodic progress reports, milestone activities and communications to the program management.
- Supports establishment and maintenance of global documentation related to the systems in scope (e.g. SOPs, WIs, user guides, etc)
- Contribute to Laboratory Operations Quality System in defining and implementation of strategy and defined activities.
- Adheres to all applicable procedures, cGMPs, company policies and any other quality or regulatory requirements.

Key Performance Indicators :

- Metrics according to target
- Individual project completion
- Achieves agreed targets and objectives in terms of quality, time and cost
- Supports departmental objectives to implement systems according to overall program plans

Minimum Requirements:

Education:

University degree in Pharmacy, Engineering, Chemistry or equivalent Discipline

Work Experience:

Experience:

Thorough knowledge of cGMP requirements:

* Computer System Validation experience is key expectation, similarly coding experience
* Strong understanding of regulatory requirements for commercial products.
* Technical understanding of laboratory business processes and enterprise data expertise

* Experience with Labware LIMS or other similar systems
* Strong understanding of risk assessment and risk management fundamentals/tools.
* Team and consensus builder, with definitive and authoritative decision-making ability.

- Critical Negotiations.
- Functional Breadth.
- Project Management.
- People Leadership.
- Collaborating across boundaries.
- Operations Management and Execution.

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

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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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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.

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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