Global System Integration Expert, Global DQC CoE

Job ID
REQ-10027504
Oct 28, 2024
India

Summary

-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 System Integration Expert supports the efforts to create system integrations via TetraScience Data platform

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

Major Accountabilities:

- Act as technical expert in creation of pipelines programmed in DataWeave programming language.
- Creates pipelines (custom code) to enable data form various laboratory systems to be transferred to the current LIMS system
- Supports establishment and maintenance of global documentation related to the systems in scope
- Identifies and anticipates site needs, determines what features should be implemented, and support prioritization
- 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.
- 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

Experience:

Thorough knowledge of cGMP requirements:

* The profile must have strong knowledge in Data Weave programming language.

* 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 and/or TetraScience data platform
* 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.

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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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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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