GLIMS Expert, Global DQC CoE

Job ID
REQ-10027493
oct 28, 2024
Inde

Résumé

-Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Job Purpose :

The Global Lab Information Management Systems Expert supports the efforts to validate 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 5 years of laboratory experience in a pharma industry.

Major Accountabilities :

- Act as the business system subject matter expert 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.
- Identifies and anticipates site needs, determines what features should be implemented, and support prioritization of the backlog items.
- 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.
- Supports deployment/on-boarding at new sites.
- 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

Education:

University degree in Pharmacy, Engineering, Chemistry or equivalent Discipline

Languages:

Fluent in speaking / writing in English

Experience:

Thorough knowledge of cGMP requirements:
* 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, and CSV
* Strong understanding of risk assessment and risk management fundamentals/tools.
* Team and consensus builder, with definitive and authoritative decision-making ability.

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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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