NOVARTIS

CSV and Data Management Analyst

Job ID
REQ-10007751
Jun 07, 2024
Mexico

Summary

Execute activities related to GxP computerized systems implementation, validation, and related activities, as well as data and user access management in ERP systems (such as SAP) in accordance with local, regional, and global standards and guidelines.

About the Role

General

- Guarantee region DI and GxP compliance according to current health authorities' regulations and applicable guidelines as well as corporate standards.
- Assist and support internal and external audits. Establish and verify timely execution of all CAPAs derived from these audits. Collaborate in appropriate resolution of all deficiencies detected during health, internal, corporate and security authorities' audits.
- Actively participate in initiatives and projects to improve Quality Assurance at a local, regional and/or global level.
- Participate in the strategy and actions for regional projects of Quality Assurance Digital Solutions, in order to create a more productive and efficient environment in QC laboratories, in accordance with Novarits' general Digital QC strategy.
- Identify, and propose solutions directed to mitigate data integrity risks throughout analytical technology use.
- Demonstrate customer-oriented service mindset in handling and executing deliverables.
- Responsible for data compilation and preparation of dashboard/data bases on regular basis to track and report deliverables.
- Report and record Issues, Deviations, Quality Events emerging from process delivered, and communicate progress as appropriate in collaboration with team leader.
- Ensure efficient, timely and clear communication to all involved partners (local and global functions) as required for follow-up on activities under scope.
- Build and maintain high expertise and continuously acquire process knowledge.
- Support and participate in the implementation and modification of processes.

Master Data and User Management Support

- Support users in applicable systems as superuser (such as SAP).
- Responsible for the data management in ERP systems such as SAP in quality modules such as (but not limited to) create/ update of inspection plans as current analytical monography, create/ update certificate profile as required.
- Review and troubleshoot issues during uploading os updating specs or creation of manual inspection lots.

Computerized systems validation

- Collaborate with local quality control laboratories in conception and execution of validation programs for computerized systems, and related activities.
- Create, and/or review validation protocols and reports for QC laboratories computerized systems, warranting a consistent and compliant approach throughout the region.
- Execute tasks related to computerized systems administration, in collaboration with the System Owner, such as User Administration, Periodic User Review, Audit Log review, etc.
- Manage electronic data backup and restoration processes with local/regional IT teams, in accordance with ISRM guidelines and Effective Procedures.

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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Division
Operations
Business Unit
Innovative Medicines
Location
Mexico
Site
INSURGENTES
Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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