Document Management Analyst

Job ID
REQ-10059976

8月 13, 2025

Mexico

摘要

Responsible for managing QMS Documents, (SOPs, WPs, WIs, FRMs, etc) issuance, updates, withdrawals & periodic reviews from initiation until completion assuring that the processes adhere to the Novartis QM directives, Global SOPs, Health Authorities requirements.

About the Role

Major accountabilities:

- Coordinate the issuance and the update of QMS Documents (including Standard Operating Procedures, Work Instructions, FRMs, etc.), in order to ensure compliance with Novartis standards & Health Authorities requirements.
- Review CAPAs Plans in order to identify required changes (Inclusions, deletions, modifications) in QMS Documents.
- Perform the role of SOP Manager and Coordinator within Electronic Document Management

Systems.
- Set and provide input on priorities for owned activities.
- Demonstrate customer-oriented service mindset in handling and executing deliverables.
- Responsible for data compilation and preparation of dashboard on a regular basis to track and report deliverables.
- Regularly communicate with customers and partners to collect feedback on support services.
- Responsible for writing and updating SOP ' s applicable to owned activities.
- Follow-up on the actions determined by audits, self-inspection, Quality Manual, etc. for the Document Management aspects.
- Ensure efficient, timely and clear communication to all involved partners (local and global functions) as required for flawless follow-up on activities under scope.
- Communicate progress and deviations as appropriate in collaboration with team leader.
- Build and maintain high expertise and continuously acquire process knowledge.

Key performance indicators:

- Document Management & Artwork processes KPIs and KQIs.
- High customer satisfaction/responsiveness (no customer complaints).
- Adherence to project timelines and proactive management of upcoming issues.
- Generation / delivery of reports related to the administration QMS Documents.
- No issues due to non-observance of cGMP, SOPs and no critical deviations.

Minimum Requirements:
Work Experience:

- Scholarship: Professional related to Chemical-Biological areas: IF, IQ, IQI, IBT, IB, QFI, QFB, QBP, LF or Project Management with Pharma experience.
- Experience/Professional: approximately one year of experience in Pharmaceutical Industry are desirable. Solid experience in data analysis and reporting.

Skills:

- Knowledge: Quality Systems; Continuous Improvement; Good Manufacturing Practices; local/international Health Regulations;
- Skills: Strives for simplicity and clarity; Digital technology Savvy; Continuous Learning; Solution oriented behavior; Self organization; Stakeholder Engagement; Organizational Savvy; Effective communication; Breakthrough analysis; Agile Mindset; Agile Teams.

Languages :

- English.

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部门
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Business Unit
Innovative Medicines

地点
Mexico

站点
INSURGENTES

Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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