

Associate Manager- RIM

Job ID
REQ-10024699

10月 08, 2024

India

摘要

-Performs the coordination and preparation of internal and external audits and compliance in accordance with regulatory standards. Collaborates with clients to develop positive and proactive approaches to regulatory compliance. Ensures that privacy and security standards are met and adhered to. May coordinate activities and assist with interactions during regulatory agency inspections. May direct interaction with regulatory agencies on defined matters. Recommends strategies for earliest possible approvals of clinical trials applications. Assists with the corrective action implementation. May coordinate investigator site and clinical supplier vendor audits.

About the Role

Major accountabilities:

- With guidance, ensures good data quality of RIM System (s) by monitoring data accuracy and completeness.

- Proactively follows up with relevant people (e.g. COs, RA CMC, HQ RA Managers) to make certain the data is updated and maintained in RIM system (s).
- Collaborates with the RIM team for implementation of new cleaning rules, and corresponding training material
- Support a compliance and quality culture within RA through effective team work and open communication
- Escalate potential compliance risks as necessary to management as appropriate
- Support implementation of RA systems in collaboration with subject matter experts and IT
- Compile regulatory compliance monitoring reports and follow ups on quality issue.
- Manage deviations/incidents/Quality Events/CAPAs in the appropriate system together with RA groups according to timelines
- Support or lead the preparation of RA for internal global audits as assigned

Key performance indicators:

- Fully compliant portfolio with internal and external regulations and procedures -Adherence to Novartis policy and guidelines -Stakeholder/ project feedback

Minimum Requirements:

Work Experience:

- Cross Cultural Experience.
- Operations Management and Execution.
- Collaborating across boundaries.

Skills:

- Scientific degree in life sciences or equivalent
- At least 2-3 years professional experience in Regulatory in Pharma or related area
- Strong knowledge of Microsoft Office Suite of applications (excel, power point, share point, OneNote, MS teams, etc.)
- Basic knowledge of the Drug Development Process and regulatory compliance for marketed products and investigational trials
- Capable to quickly learn and understand how to use RA systems
- Good interpersonal and communication skills, both oral and written
- Good analytical skills, ability to produce meaningful reports from RA systems
- Precise and independent working style with a high sense of responsibility and initiative
- Logical and methodical, with attention to details

Languages :

- English.

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部门

Development

Business Unit

Innovative Medicines

地点

India

站点

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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