

Associate Manager- RIM

Job ID

REQ-10024699

08 Oktober 2024

India

Samenvatting

-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.

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Afdeling

Development

Business Unit

Innovative Medicines

Plaats

India

Site

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

[Apply to Job](#)

Accessibility and accommodation

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.

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }

Job ID

REQ-10024699

Associate Manager- RIM

[Apply to Job](#)

Source URL: <https://www.novartis.com/be-nl/careers/career-search/job/details/req-10024699-associate-manager-rim>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Associate-Manager--RIM_REQ-10024699
5. <mailto:diversityandincl.india@novartis.com>
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Associate-Manager--RIM_REQ-10024699