

Risk Surveillance Lead

Job ID

REQ-10076078

Aug 07, 2026

LOC_IN

About the Role

Major Accountabilities:

- Facilitate trial protocol risk assessment across multiple cross-functional domains (clinical, operational, data management, vendors, regulatory etc.) associated to critical-to-quality (CtQ) data and processes, including definition of quality tolerance limits (QTLs), evaluation of risks based on likelihood, detectability, impact, and ensures mitigation strategy / plans are defined
- Responsible for drafting, maintaining, and archiving the study specific documentation of risk management activities e.g., Integrated Quality Risk Management Plan (IQRMP)
- Partners with the RBQM system configuration team to ensure risk indicators, quality tolerance limits and other analytics/visualizations are programmed and functioning per operational requirements in the RBQM system
- Conduct of periodic central surveillance of the aggregate data at the study and potentially program level, leveraging available analytics/visualizations in the RBQM system, to identify emerging risks and/or issues
- Facilitate risk review meetings and discussions with study and potentially program team members to effectively communicate and discuss the findings, support, and encourage robust root cause identification and mitigation strategies
- Supports and participates in internal and external audits and inspection
- Collaborate with training departments to support training initiatives and aid in the adoption of the RBQM approach.
- Identifies and shares lessons learned, best practices, successes, case studies, failures, and process improvement opportunities to promote continuous improvement and consistency with RBQM processes
- Acts as a change agent, champion, subject matter expert and point of contact of RBQM methodology, leading study teams to understand and follow the best practices to achieve maximum benefit

Experience:

Bachelor's Degree in a health-related, life science area, or equivalent combination of education, training, and work experience

- Minimum of 4 years of experience in the pharmaceutical or CRO industry
- Preferred minimum of 1 years of experience in Risk Based Quality Management
- Robust understanding of the drug development process and clinical trial execution
- Knowledge of industry regulatory standards including 21 CFR Part 11, ICH E6, ICH E8 (GCP)
- Experience in risk management, sponsor audits and health authority inspections, root cause analyses and mitigation strategies as well as Corrective Actions Preventive Actions
- Knowledge of RBQM IT systems or other data analytic systems
- Demonstrated ability to analyze data, identify patterns and make recommendations for improvement
- Demonstrated ability to effectively lead cross functional team meetings
- Experience forming cross-functional collaborations; strong interpersonal skills
- Supports a culture of continual improvement and innovation; promotes knowledge sharing
- Ability to influence without authority
- Thinks creatively; challenges the status quo

Languages:

English: fluent written and spoken

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

Commitment to Diversity and Inclusion / EEO

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Role Requirements

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.

[Read our handbook \(PDF 30 MB\)](#)

Division

DIV_GD

Business Unit

Development

Location

LOC_IN

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

FCT_RD

Job Type

Full time

Employment Type

Regular

Shift Work

No

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