

Risk Surveillance Lead

Job ID
REQ-10077729
июл 28, 2026
Испания
Available in: English

Сводка

The Risk-Based Quality Management (RBQM) Risk surveillance Lead is responsible driving the adoption of RBQM practice at trial level and oversee the implementation, and continuous improvement. Risk Surveillance Lead works within a matrix environment and has overall account-ability for the surveillance of the quality risks across the assigned trials and program, enabling a comprehensive clinical quality (GCP) risk governance. The role demonstrates leadership in influencing and improving clinical trial quality through the expert understanding of clinical trial protocols, processes, regulatory requirements, and quality management principles.

Please note that Novartis cannot sponsor visas for this location. Relocation is not available.

#LI-Hybrid
On site expectation of 12 days per month/ave. 3 days per week in the office.

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

- **Benefits & Rewards**At Novartis, we're committed to reimagining medicine together - and rewarding the people who make it happen.The expected Annual Base Salary Range for this role: 63,600.00 - 118,000.00 EUR AnnualThe base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.Pay equity is a fundamental principle of our employment policy and reflects our commitment to create a diverse, equitable and inclusive environment that treats all employees with dignity and respect, as outlined in our Code of Ethics. Read our brochure to learn more about our global total rewards offering: <https://www.novartis.com/sites/novartis.com/files/novartis-life-handbook.pdf> *Note: Benefits and compensation may vary by country and are subject to*

local legal requirements, including provisions of collective bargaining agreements where applicable. A full overview of your compensation package, including any relevant collective bargaining agreement details applicable to your role based on your employment location and Novartis employer entity, will be communicated separately to you during the application process. **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.

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 \(PDF 30 MB\)](#)

Primary location salary range
€63,600.00 - €118,000.00
Дивизион
Development
Business Unit
Development
Место
Испания
Сайт
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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