

Risk Surveillance Lead

Job ID

REQ-10017287

Aug. 20, 2024

Vereinigtes Königreich

Zusammenfassung

Responsible for driving the adoption of RBQM practice at trial level, oversee the implementation, and continuous improvement. The Risk Surveillance Lead works within a matrix environment and has overall accountability 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.

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 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 / 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
- May perform line management of other (junior) staff within RBQM Team

Key performance indicators:

- Adoption rate of RBQM across trial portfolio

- Effectiveness in risk identification, assessment, and mitigation (number of risks identified, assessed, and successfully mitigated).
- Stakeholder satisfaction measured through structured feedback and surveys conducted periodically.
- Insights generated from metrics leading to Process and Quality Risks improvements.

Minimum Requirements:

Work Experience:

- Minimum of 6 years of experience in the pharmaceutical or CRO industry
- Minimum of 2 years managerial and supervisory experience
- 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

Skills:

- Risk Management.
- Risk Monitoring.
- Budget Management.
- Clinical Research.
- Clinical Trials.
- Coaching.
- Cross-Functional Teams.
- Lifesciences.
- People Management.

Languages :

- English.

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