NOVARTIS

Associate Director, Quality Evaluations, Integrations, and External Services

Job ID
REQ-10075831
апр 13, 2026
Китай

Сводка

The BR Quality Operations role is primarily responsible for managing and executing quality related operational activities, continuous improvement initiatives and for leading/supporting execution of Quality Due Diligence (DD) activities, related integration, and Third-Party oversight. The role is responsible for assuring compliance to regulatory and internal standards/guidance of operational and BD&L / M&A activities within respective/assigned areas.

The role leads/supports the focused (where applicable) and confirmatory due diligence to identify potential quality gaps, risks, and issues in a proactive manner, proposes mitigation, and ensures transparency throughout the DD through integration process. Escalates where applicable and briefs BR Quality and DD management.

About the Role

Major Activities

- Executes Quality Operational & continuous improvement activities.
- Responsible for all relevant Due Diligence, Integration, and Third-Party management activities as outlined in the applicable procedures.
- Conduct focused (where applicable) and confirmatory due diligence to detect quality assurance risks, trends and to identify potential quality and performance issues with in-licensed medicinal products and/or inclusive product portfolio in cases of acquisition.
- Collaborate with BD&L / M&A DD teams to ensure timely communication of risks to the business and follow-up on required actions for respective QA areas of expertise/focus.
- Owner of inputs to the overall DD report for assigned QA focus area and input to finalize QA due diligence report in collaboration with BD&L QA Partners per defined timelines.
- On assignment of applicable integration activities, partner with respective integration teams to execute/ oversee QA remediation activities and action plans for assigned QA focus area.
- Provides support for internal and external audits and inspections.
- Lead/Participate relevant Third Party (vendor oversight) quality activities including CRO selection, governance, and performance monitoring) as outlined in applicable procedures.
- Collaborates with internal business partners, R&D Procurement and other Novartis functions to participate in vendor selection and strategic planning, review quality requirements, perform risk evaluation and follow-up on required actions.
- Drive quality initiatives and continuous improvement for internal & out-sourced activities to assure compliance with regulations & Quality procedures and implement operational quality efficiencies.
- Fulfill Functional Representative (FR) responsibilities for designated projects and activities.

Ideal Background

- Ph.D. or Masters in Life Sciences, Pharmacy or Medi-cines.
- Demonstrated quality/scientific operations experience with a minimum of 8 years (AD) 4 years (Manager) working in a pharmaceutical industry with knowledge of R&D programs (research, preclinical safety, bioanalytics and clinical)
- Broad understanding and interpretation of regulatory requirements understanding of Industry Quality Standards and International Regulations (OECD, FDA, GLP, GCP)
- Expertise in managing third parties and in conducting internal / external scientific & quality assessments
- Familiarity with chemical / bio analytical methods, Cell & Gene /Radio Ligand / xRNA platforms, Cell and Molecular Biology, Animal Welfare is a plus.
- Strong leadership experience including excellent communication, collaboration/consensus building, considerable organizational awareness, influencing and negotiation skills.
- Demonstrated ability to lead and partake interdisciplinary-nary projects with scientific, finance, and/or commercial business functions and successfully work in a global cross-functional matrix.
- A clear sense of personal accountability, an ability to empower people, ability to drive quality culture with partners and a high degree of mutual respect and integrity are essential factors to succeed.
- Strong risk management skills, ability to balance with strategic benefits, and to translate appropriately.
- Strong customer focus and quality driven

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)

Дивизион
Biomedical Research
Business Unit
Research
Место
Китай
Сайт
Shanghai (Shanghai)
Company / Legal Entity

CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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

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.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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