

# Associate Director, Quality Evaluations, Integrations, and External Services

Job ID  
REQ-10075831  
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## 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

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<https://www.novartis.com/about/strategy/people-and-culture>

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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

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