

AD, QA, Evaluations and Integrations

Job ID
REQ-10027163
Oct 25, 2024
USA

About the Role

Key Responsibilities:

- Establish or participate to cross-functional teams and act as single point of contact for BD&L DD QA and support QA assessments for corporate and BR BD&L or M&A Due Diligence and Integration projects as required. Ensure representation of QA SMEs for all necessary functions.
- Ensure open and effective communication and business partnership with all stakeholders.
- Oversee the implementation and handover of deals by QA SMEs to the relevant LF. Provide the Quality and Technical expertise needed in the Quality Integration process or facilitate input from SMEs where specialist knowledge is required.
- Prioritizes, resolves issues and ensures escalation to management.
- Represent QA at BD&L DD relevant forums as determined by management
- Ensure quality and compliance gaps are addressed and executed for sustainability and implement strategic process improvement, including review of procedural updates, training, effectiveness checks, etc.
- Support quality oversight/management of external service providers supporting research and development activities and drive facilitation and follow-up of audits and inspections, and ensure development, implementation and completion of appropriate corrective and preventive measures for findings -Ensure timely escalation of deviation/incidents and provide quality oversight for deviations/incidents, including robust investigations, root cause analysis and corrective actions implementation.
- Contribute towards lessons learned based on audits, inspections, incidents, regulatory intelligence, effectiveness checks on process implementations and metrics and support a culture of proactive, risk-based behavior

Essential Requirements:

- Bachelor's Degree in Chemistry, Pharmacy / Biotechnology, Microbiology or other related science
- MS/PhD preferred
- Minimum 10 years' experience in the biopharmaceutical industry, including operational experience in R&D, which include 5 years in Quality.
- Broad understanding of global expectations of Health Authorities in GxP regulated areas.
- 5 or more years of demonstrated leadership and accomplishments in an (international) matrix organization.
- GxP audit familiarity
- Critical Negotiation Skills
- Operations Management and Execution

- Project Management

The pay range for this position at commencement of employment is expected to be between \$158,400 and \$237,600 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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>

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Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division

Biomedical Research

Business Unit

Pharma Research

Location

USA

Site

Cambridge (USA)

Company / Legal Entity

U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc.

Alternative Location 1

USA

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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