Associate Director, Research Quality

Job ID
REQ-10035764
Jan 16, 2025
USA

Summary

This position will be located at San Diego site and will not have the ability to be located remotely. This position will require minimal travel as defined by the business (domestic and/ or international).
The Associate Director Research Quality is responsible for the development, implementation and management of the quality program applicable to the wide range of discovery science and scientific research activities conducted within NIBR globally.
#LI-Onsite
Key Responsibilities:
This role will be responsible for this role in Research Quality (RQA):
1. Establish research quality standard & compliance monitoring program focusing on internal customer satisfaction and sustained compliance to data quality & integrity standards, policies for Human Tissue use, data privacy and regulatory requirements. Establish a continuous improvement program.
2. Lead evaluation for monitoring the performance of the existing Research & Lab processes and systems for the identification of potential quality and Data Integrity gaps. Work effectively in a matrix environment to develop, propose and implement processes across BR to ensure good data management and sustained compliance.
3. Lead/supervise/participate in the review of research and laboratory project documentation (e.g. Lab notebooks and systems) for both internal processes and external collaborators to assess for Data Quality & Integrity. Provide BR Quality management with reports on the results of the reviews. and support issue resolution and closure.
4. Maintain an awareness of quality issues that impact scientific and business objectives. Interact with internal and external departments to provide interpretation of Quality & Compliance information to meet business and regulatory requirements and provide an understanding of how aspects of external requirements may impact the BR organization.
5. Collaborate with BR business partners to support the development of scientific discoveries & research innovation utilizing risk based and mitigation quality processes.
6. Lead and support Quality Due Diligence for Business Development and Licensing Agreements. Review the Quality of the preclinical data for potential assets in the due diligence process and make recommendations to the greater Due Diligence Team.
7. Review industry trends for GxP and non-GxP regulated areas applicable to the NIBR Research areas and recommend appropriate and timely action.
8. In coordination with the Training department and internal customer needs, ensure the required Data quality & Integrity training is established. Establish, report and monitor KPIs related to the program for continuous improvement.
9. Promote a robust quality culture across Non-GxP research & Lab. Train, and educate scientists and other QA associates in Data Quality & integrity and quality system requirements, in terms of its content, delivery and

strategic importance.
10. Provide expert knowledge in the use of Human Tissue samples in research and have the ability to interpret and provide guidance on country specific regulations. Work in a matrix environment with Legal and Data Privacy to implement the relevant practices.

About the Role

Requirements:

- Ph.D. in a Scientific and/or Engineering discipline preferred and/or related equivalent experience.
- Demonstrated experience in a senior Compliance and Qual-ity System role.
- 10+ years broad experience in a scientific/pharmaceutical industry. Experience in a Biomedical research environment is considered a plus.
- Strong strategic vision and superior leadership experience including excellent communication, collaboration/consen-sus building, influencing and negotiation skills
- Demonstrated ability to partake or lead cross-functional projects and to effectuate change within a high-performing organization.
- Experience in coordinating/integrating with a wide range of business functions and success working globally in multi-disciplinary teams.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $145,000 and $270,400/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. 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.

Company will not sponsor visas for this position.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 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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Pharma Research
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Alternative Location 2
Boston (Massachusetts), Massachusetts, USA
Alternative Location 3
Emeryville (California), Californie, USA
Alternative Location 4
San Diego (California), Californie, USA
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Quality
Job Type
Full time
Employment Type
CDI
Shift Work
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