Expert Science & Technology, QC Bioanalytics (Tuesday-Friday)

Job ID
REQ-10025057
Nov 25, 2024
USA

Summary

Internal Job Title: Expert Science & Technology
Position is on-site in East Hanover, NJ
#LI-Onsite

About the role:
Novartis expands its early development and innovative CAR-T cell therapy manufacturing capabilities in its newly launched Center of Excellence, located in the East Hanover, NJ campus. Our therapies are being developed as transformative treatments with life-saving potential for various B cell malignancies and other oncological diseases. We look to be bold with purpose, as we reimagine medicine and lead the way in advancing scientific breakthroughs for patients.

The Expert, Science & Technology position will manage Quality aspects of clinical programs and projects within area of responsibility. Ensure and support overall GxP conformity and Compliance with the Novartis Quality Management Systems. Identify and execute on OpEx opportunities. Build/manage stakeholder relationships and expectations
• **Shift position** 8am-6pm Tues- Friday and weekend coverage as needed. Shift will be fixed according to business need.

About the Role

Your Key Responsibilities:

Your responsibilities include, but are not limited to:

- *Shift position** 8am-6pm Tues- Friday and weekend coverage as needed. Shift will be fixed according to business need. Shift will be fixed according to business need.
- Perform bioanalytical testing and support activities compliantly following appropriate SOPs and procedures. Peer review and archive analytical data in lab documentation systems.
- Draft, finalize and revise technical protocols, procedures, and reports with minimal supervision.
- Support execution of method qualification/development & optimization/transfer as governed by protocols and/or under the supervision.
- Train other associates in specific areas of competency.
- Lead and/or contribute to writing CAPAs/OOS/OOE/OOT and perform deviation investigations.
- Knowledge of LabWare, LIMS and/or other QC data systems.
- Ensures that processes are conducted in full compliance with the GxP and the Novartis Quality.

- Contributes to an improvement of current processes and/or to an implementation of modified processes.
- Review quality deliverables to ensure compliance, with health authority requirements and SOPs, including procedural documents, records, third party work, contractors, clinical trial material, components, and gap assessments -Prepare and review GxP documentation; assists in the release of GxP documentation, filing and archiving of GxP documentation

Role Requirements:

- Bachelor's degree in cell biology, immunology, molecular biology, virology, biochemistry, microbiology, or other related science. Advanced degree may be an advantage but not essential.
- Minimum of 3 years of experience in the pharmaceutical, biologics, Biotechnology, or medical device industry, ideally in a QC laboratory setting.
- Thorough knowledge of bioassay test methods (Elisa, flow cytometry, qPCR, cell culture) is required.
- Strong written and verbal communication skills are essential.
- Experienced in the use of computer -based systems and applications.

Desired Requirements:

- Good understanding of the concepts of cGxP and knowledge of ICH, Eur. Ph., USP and FDA and JP guidelines is preferred.
- Experience in support/writing OOS/OOE/OOT and/or deviation investigations and knowledge of CAPA is preferred.

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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Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $84,000-$126,000; *however, while salary ranges are effective from 1/1/24 through 12/31/24, 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.

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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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Business Unit
Innovative Medicines
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USA
Site
East Hanover
Company / Legal Entity
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Functional Area

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Job Type
Full time
Employment Type
Regular
Shift Work
No
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REQ-10025057

Expert Science & Technology, QC Bioanalytics (Tuesday-Friday)

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