NOVARTIS

Senior Expert Science & Technology - Quality Control Information Technology

Job ID
REQ-10015318
Juli 30, 2024
USA

Summary

#LI-Onsite. Location is East Hanover, NJ.

Title: Senior Expert Science & Technology - Quality Control, Information Technology

As a key member of the Analytical Development and Operations team, this individual will support developmental activities to aid in delivering gene therapy to patients. The successful candidate will support the lifecycle management of GxP lab systems in the Cell and Gene Therapy analytical labs in Novartis Technical Research & Development (TRD) from concept, development, validation, implementation and maintenance to retirement. Growth mentality and passion to serve patients, his/her technical team and development programs is a must.

About the Role

Major accountabilities:

- Acts as the SME for GxP lab systems such as LIMS, Empower, and other analytical instruments in the analytical labs in TRD CGT
- Ensures the GxP lab systems are in compliance to all regulatory requirements such as 21 CFR Part 11 and Annex 11.
- Day-to-day management and continuous improvement of all GxP lab systems/processes.
- Plans and leads large GxP system projects, such as LIMS implementation and lab instrument qualification.
- Works with Analytical Development and Operation teams, IT, Engineering, and Validation to support GxP lab system lifecycle management activities from concept, development, validation, implementation and maintenance to retirement.
- Authors, reviews, reports on and approves corrective actions to protocols, investigations, non-conformance, CAPAs, and other records related to GxP lab systems.
- Leads data integrity initiatives related to GxP lab systems.
- Reviews, identifies, and leads implementation of improvements to existing lab systems.

- Overseas/Creates SOPs and training related to GxP lab systems.
- Lead representation of GxP lab systems during meetings.
- Oversees and/or communicates and tracks all follow-up items through to completion.
- Other related duties as assigned.

Minimum Requirements:

- Bachelor's degree in Biology, Biochemistry, Molecular Biology, Immunology or related scientific discipline with > 4 years of prior experience in academia or industry
- At least 4 years experience in a GMP laboratory preferred.
- Experience in instrument administration (esp. In CGT area). LIMS administration a plus.
- Experience with chromatography data systems, such as Chromeleon, Waters Empower®.
- Advanced working knowledge of Windows permission settings, network domain, and a general understanding of server architecture is a plus
- Working knowledge in SQL, Java, or other LIMS programming language.
- Experienced in lifecycle management of GxP lab systems.
- Experience working with AAV, LVV and cell therapy analytics preferred.

The pay range for this position at commencement of employment is expected to be between $136,000 and $205,200/year; 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.

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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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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