

Expert/Senior Expert Science & Technology - Good Manufacturing Practices

Job ID
REQ-10015319
Juli 23, 2024
USA

Summary

#LI - On site. Located in East Hanover, New Jersey.

Title: Expert/Senior Expert Science & Technology - Good Manufacturing Practices

As a key member of the Analytical Operations team, this individual will support GMP activities to aid in delivering gene therapy to patients. The successful candidate will support development projects designed to release and characterize gene therapy products through an assortment of analytical methods. This role will also contribute to cross-functional activities including monitoring of processes and products to identify opportunities for continuous improvement. Growth mentality and passion to serve patients, his/her technical team and development programs is a must.

About the Role

Major accountabilities:

- Serves as SME (Subject Matter Experts) in several Good Manufacturing Practices (GMP) assays, such as AUC (Analytical Ultracentrifugation), cell-based potency, ELISA (Enzyme Linked Immunosorbent Assay), PCR, flow cytometry, next generation sequencing and separation assays.
- Plays an active role in establishing the site GMP lab operations to support development and commercialization of new gene therapy medicines.
- Routine sample testing under GMP or non-GMP modes (in-process, release, and stability), laboratory maintenance, and participating in method qualification, validation, transfer, and improvement. Reviews and trends results.
- Manages the procurement, implementation, use, and maintenance of equipment, instrumentation, and computer systems.
- Writes and revises documents such as SOPs (Standard Operation Procedures), method validation/transfer protocols, and technical reports.
- Leads investigations to determine root cause of deviations and non-conforming results and implement appropriate corrective and preventative actions in a timely manner.
- Identifies and implements innovative technologies to improve the compliance and efficiency of GMP

operations.

- Represents GMP to work with other departments including Analytical Development, Quality Assurance, and Manufacturing to address compliance issues and to implement corrective actions and to improve programs.
- Work according to appropriate GMP/GLP regulations and Novartis SOPs/Guidelines and Code of Conduct.
- Other related job duties as assigned.

Minimum Requirements:

The level of this role will be commensurate to candidate's experience and education.

Expert:

- Bachelor's degree in Biology, Biochemistry, Molecular Biology, Immunology or related scientific discipline with > 3 years of prior industry experience required.
- At least 2 years experience in a GMP laboratory preferred.
- Moderate understanding and working knowledge of principles and theories in analytical chemistry, protein chemistry, DNA chemistry and related disciplines.
- Quick learner, highly motivated, hard-working and detail oriented.
- Demonstrated ability to work collaboratively in a fast-paced team environment and quickly acquire new technical skills and knowledge
- Excellent written and verbal communication skills.

For Sr. Expert:

- 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.
- Possess strong understanding of GMP testing operations and provide expertise in several assays such as AUC, cell-based potency, flow cytometry, ELISA, PCR, and separations-based assays.
- Ability to work independently on problem solving, lab investigations, and implementation of preventative and corrective actions.
- Ability to work effectively within the group, within Quality, and across sites. Additional responsibilities include adherence to all GMP requirements, an understanding of FDA/EMEA regulations, effective interactions/communication with Quality management.
- Demonstrated ability to work collaboratively in a fast-paced team environment and quickly acquire new technical skills and knowledge

The pay range for this position at commencement of employment is expected to be between \$84,000 and 126,000 for Expert & \$112,800 and 169,200 for Senior Expert /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>

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>

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Division

Development

Business Unit

Innovative Medicines

Standort

USA

Site

East Hanover

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.

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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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