NOVARTIS

Expert/Senior Expert Science & Technology - GMP

Job ID
REQ-10015319
Jul 23, 2024
Estados Unidos

Resumen

#LI - On site. Located in East Hanover, New Jersey. 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 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 > 2 years of prior industry experience required. BS with > 5 years, MS with >2 years, Ph.D. with >1 year experience preferred
- Strong understanding and working knowledge of Cell Biology, protein, and DNA chemistry.
- Strong understanding and working experience with cell-based assays and other plate-based assays using variety of platforms including ELISA, flow cytometry, PCR, MSD, high-content imaging, and luminescent/fluorescent plate reader.
- Quick learner, highly motivated, hard-working and detail oriented.
- Expertise with aseptic technique and mammalian cell culture experience a plus
- Strong ability to work in a fast-paced team environment with highly goal-oriented approaches and to prioritize work from multiple projects with can-do attitude is required.
- Excellent written and verbal communication skills.
- Established ability to work in a regulated environment.

Desirable Experience:

- Good presentation skills and scientific/technical writing skills
- Experience working with AAV, LVV analytics preferred.

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 $102,400 - 153,600 for Expert & $124,000 - 186,000 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

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.

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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.

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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