Senior Expert - Good Manufacturing Practices

Job ID
REQ-10026853
Nov. 27, 2024
USA

Zusammenfassung

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

Key Responsibilities:

Shift work schedule might be required (4 days per week 10 hours per day, 8 am - 6 pm and/or 10 am - 8 pm)

- 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.

Essential 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.
- 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 $118,000 and 177,600/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.

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

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.

Abteilung
Development
Business Unit
Innovative Medicines
Ort
USA
Status
New Jersey
Website
East Hanover
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area

Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID
REQ-10026853

Senior Expert - Good Manufacturing Practices

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10026853-senior-expert-good-manufacturing-practices*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. mailto:us.reasonableaccommodations@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/East-Hanover/Senior-Expert_REQ-10026853-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/East-Hanover/Senior-Expert_REQ-10026853-1