

Senior Expert, Good Manufacturing Practice

Job ID
REQ-10026968

11月 19, 2024

USA

摘要

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:

This role may require 10 hours (8 am - 6 pm; 10 am - 8 pm) a day, 4 days a week shift.

- Serves as SME (Subject Matter Experts) in analytical method qualification, transfer, validation and life cycle management for several GMP assays, such as AUC (Analytical Ultracentrifugation), cell-based potency, ELISA (Enzyme Linked Immunosorbent Assay), PCR,(qPCR and dPCR) 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.
- Design, participate and/or oversee method qualification/transfer/validation strategy, protocol and execution.
- Routine sample testing under GMP or non-GMP modes (in-process, release, and stability), laboratory maintenance and reviews and trends analytical 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.
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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.
- Strong expertise in method qualification/validation/transfer and familiarity with ICH guidelines
- 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.

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部门

Development

Business Unit

Innovative Medicines

地点

USA

站点

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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