

Expert, Drug Supply

Job ID
REQ-10051831

5月 19, 2025

USA

摘要

Title: Clinical Lab Tech and Science Support

This position will be located at East Hanover, NJ site and will not have the ability to be located remotely.

“Please note that this role would not provide relocation and only local candidates will be considered.”

Provides input to developing validation strategy and coordinating validation activities required to complete assigned validation projects in support of the operation of the East Hanover, NJ facility according to the corporate policies, SOPs, cGMPs, QMs and international regulations. Provides technical support and services to the Quality Assurance, Regulatory, and Process Unit Departments.

#LI-Onsite

Key Responsibilities:

- Assist in maintaining the process control strategy. Translate applicable process parameters and the process control strategy into a focused validation plan for process validation.
- Provide technical expertise and facilitate establishment of Quality Risk Assessment (as needed).

- Review Master Batch Records and assesses, maintains and/or owns change controls.
- Support Technology Transfer activities on as needed basis
- Lead, plan and maintain all activities related to aseptic processing validation with consultation of Associate Director, Validation. Support routine and non-routine Aseptic Process Validation activities by writing protocols and summary reports. Ensure that appropriate variables are identified for on-going monitoring as a contributor to quality risk management activities.
- Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing process verification (OPV) / continued process verification (CPV) as applicable to enable late stage studies.
- Author and review process, process development, aseptic processing validation, and shipping validation protocols & reports, ongoing process verification protocols/plans & reports.
- Plan and support execution of validation activities on the floor.
- Support Associate Director, Validation for KPI reporting.
- Maintain all activities and projects under own responsibility in an inspection ready status
- Support evaluation of new and existing processes being transferred to or from the site by utilizing risk-based approach.

About the Role

Requirements:

- BSc. in Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology. Preferred
- 3-5 years experience in manufacturing/ manufacturing science and technology/technical development/quality.
- Thorough understanding of manufacturing processes and related process equipment.
- Strong working knowledge of quality systems and regulatory requirements across multiple health authorities.
- Experience in executing process validation.
- Expert in reviewing and writing technical documents.
- Proven project management experience in a cross-functional environment (e.g. multi-site,

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$77,000/year and \$143,000/ year; however, while salary ranges are effective from 1/1/25 through 12/31/25, 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.

Company will not sponsor visas for this position.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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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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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.

部门
Development

Business Unit
Innovative Medicines

地点
USA

状态
New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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