Associate Scientist, Raw Materials

Job ID
REQ-10027865
Nov 06, 2024
USA

Sommario

365 days a year, we aspire to be the best manufacturer of Cell & Gene therapies to ensure our patients have the treatments they need to live longer, healthier lives.
Under general direction; the Associate Scientist, Raw Material will direct and assist in functions supporting QC raw materials.

About the Role

Location: Onsite - Morris Plains, NJ

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Under general direction; the Associate Scientist, Raw Material will direct and assist in functions supporting QC raw materials.

Major accountabilities:

• Perform raw material testing following United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and in-house methods
• Perform testing on raw materials per using pH, Osmometer, Flow Cytometry, qPCR, UV, FTIR, NIR, wet chemistry and other techniques.

• Perform visual inspection of raw materials, consumables and packing materials using AQL/specification requirements.
• Perform all testing and activities compliantly following appropriate SOPs and procedures.

• Review data generated by other team members.
• Review QC documents to ensure completeness, accuracy, consistency and clarity.
• Perform quality impacting assessments and make decisions.
• Participate special projects and facilitate any issues that arise.
• Assist with initiating change controls.
• Assist with authoring validation documentation.
• Assists with investigations of complexity
• Assist with investigations to understand root cause.
• Participate in OOS/OOE investigation
• Participate in deviation investigation/CAPA implementation in a timely manner
• Evaluate compendial updates against internal methods
• Serve as Quality Control representative on cross-functional teams.

• Knowledge of LabWare LIMS and/or other QC data systems.
• Knowledge of appropriate GMP/GLP quality systems (eSOPs, TEDI, etc.).
• Assist with planning and scheduling activities.
• In addition to these primary duties, provide coverage for all appropriate areas.

• Perform other job duties as assigned.
• Ability to lift 35 pounds

Role Requirements:

• Bachelor's degree in Biology, Chemistry, Biochemistry, Microbiology or other related science. MS or advanced degree in preferred
• Fluent in English
• A minimum of 1 year of relevant experience in the pharmaceutical, biologics, or medical device industry
• Knowledge of cGMP and an understanding of the concepts of GLP, good clinical practices and ICH guidelines, applicable state and foreign regulations, and standards routinely used in the industry (i.e. ANSI, ISO, etc.)
• Thorough knowledge of raw material test methods
Desirables:
• Analytical chemistry knowledge to facilitate investigation is desired
• Knowledge of LIMS systems is desired
• Change controls or CAPA experience is desired
• Ability to communicate clearly with a variety of individuals in various aspects of Novartis operations
• Detail-oriented with expertise in problem solving and solid decision making abilities.
• Strong interpersonal skills which include a professional demeanor when interacting with Novartis personnel.
• Sound, practical and appropriate regulations with regards to Novartis
• Strong written and verbal communication skills are essential

The pay range for this position at commencement of employment is expected to be between $33.31 to $49.94 hourly; 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.or individual department/team performance, and market factors.

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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EEO Statement:

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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.

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REQ-10027865

Associate Scientist, Raw Materials

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