Expert Science & Technology, Microbiology

Job ID
REQ-10014173
Jul 22, 2024
Estados Unidos

Resumen

Internal Title: Expert, Science & Technology Position is on-site in East Hanover, NJ #LI-Onsite About the role: Novartis expands its early development and innovative CAR-T cell therapy manufacturing capabilities in its newly launched Center of Excellence, located in the East Hanover, NJ campus. Our therapies are being developed as transformative treatments with life-saving potential for various B cell malignancies and other oncological diseases. We look to be bold with purpose, as we reimagine medicine and lead the way in advancing scientific breakthroughs for patients. Under general direction, the Expert, Science & Technology associate will perform microbiological and EM testing and execute other activities and functions to ensure the timely testing and release of products related to development/clinical operations in East Hanover, Cell and Gene Therapy GMP facility. Deliver quality products and services on time to all customers, internal and external. Monitor processes and products to identify opportunities for continuous improvement. Lead technical projects and collaborate with the team in the design and execution of validation and other projects. Serve as the subject matter expert on specific areas and techniques. **Shift Position**

About the Role

Your Key Responsibilities:

Your responsibilities include, but are not limited to:

- This is a Monday-Friday 12pm-8pm shift position with rotations on the weekend. Shift will be fixed according to business needs.
- Perform micro and EM testing in support of clinical release strategies and perform all testing and activities compliantly following appropriate SOPs and Work Procedures.
- Document results within electronic and paper-based systems accordingly. Enter/review data in LIMS as applicable.
- Perform review of analytical data and archiving in lab documentation systems. Review QC documents to ensure completeness, accuracy, consistency, and clarity.
- Maintain controls and reference standards/materials to support testing.
- Perform laboratory/equipment cleaning as per applicable schedules and procedures and ensure cleanliness of laboratory working areas.
- Draft, finalize and revise technical protocols, procedures, and reports with minimal supervision.
- Support and/or manage tracking and trending systems, and programs that assist in the testing, evaluation and monitoring of quality, assay performance and efficiency.
- Support external teams in qualifying new and/or replacement equipment within the laboratory.
- Ensure assigned analytical methods are ready to be performed when required including management of reagent, consumables, and equipment inventory.

- Support execution of method qualification/development & optimization/transfer as governed by protocols and/or under minimal supervision.
- Train other associates in specific areas of competency.
- Support/manage shipments and communications to external testing sites and support laboratory management in drafting analytical response/strategy documents.
- Prepare presentations as required.
- Identify and execute process improvements, lead and/or contribute to writing CAPAs/OOS/OOE/OOT and perform deviation investigations.
- Support change control as required, support internal and external audits of facilities, follow GxP quality policies and procedures and drive 5S and Lean Lab projects.
- Assist equipment and metrology teams in troubleshooting equipment issues, working knowledge of LabWare, LIMS and/or other QC data systems.
- Ensure all assigned training is completed within the required time frame.
- Greater exposure and knowledge of internal and external guidance, good compliance in appropriate GMP quality systems (e.g., ESOPs, Subway, Trackwise, BMRAM, 1QEM and CONDOR etc.).
- Coordinate cross-functional activities, serves as a QC/Micro representative in cross- functional teams.
- Perform other job duties as assigned.

Role Requirements:

- Bachelor's degree in biology, chemistry, biochemistry, microbiology or other related science. MS is preferred.
- Minimum of 3 years of relevant experience in **one of the following** pharmaceutical, biologics, microbiology, sterile manufacture, cell and gene therapy, or medical device industry.
- Working knowledge of aseptic manufacturing, cGMPs, GLPs and applicable compendial and regulatory guidelines (e.g., FDA, EP, JP)
- Thorough knowledge of microbiological test methods and environmental monitoring programs.
- Experience with LIMS.
- Experience in support/writing OOS/OOE/OOT and/or deviation investigation.
- Strong written and verbal communication skills.
- Detail-oriented with expertise in problem solving and solid decision-making abilities.
- Strong interpersonal skills.

Desired Requirements:

- Gowning Qualified
- Environmental monitoring and qualification of cleanrooms
- Knowledge of Microbiology Test methods including but not limited to Sterility, Growth Promotion, Microbial Identification and Endotoxin testing

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to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $84,000-$126,000; *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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know the nature of your request and your contact information. Please include the job requisition number in your message.

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