QC Associate Expert Microbiology

Job ID
REQ-10020603
Sep 05, 2024
USA

Summary

Internal Job Title: Associate Expert Microbiology
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.

The Associate Expert Science & Technology will under general direction, perform microbiology/EM testing and other activities in functions supporting the Quality Control department.

**2nd Shift: M-F 12pm-8pm with rotating shift weekends.

About the Role

Your Key Responsibilities:

Your responsibilities include, but are not limited to:

- **Shift position** 2nd Shift: M-F 12pm-8pm with rotating shift weekends. Shift will be fixed according to business need.
- Perform micro/EM testing in support of clinical release strategies.
- Perform all testing and activities compliantly following appropriate SOPs and procedures.
- Maintain controls and reference standards to support testing.
- Executes and follows SOPs, WPs, and quality policies and peer review and archive analytical data in lab documentation systems.
- Support monthly/quarterly laboratory cleaning.
- Appropriate use of laboratory logbooks and monthly laboratory cleaning.
- Manage reagent/consumable inventory and equipment cleaning for assigned areas of responsibilities.
- Ensures cleanliness of laboratory working areas, support and author OOS/OOE/OOT and deviation investigations.
- Participate in CAPA implementation in a timely manner and follow GxP quality policies and procedures.
- Ensures all assigned training is completed within required time frame.

- Support 5S and Lean projects, identify process improvements.
- Knowledge of LabWare, LIMS and/or other QC data systems and appropriate GMP/GLP quality systems (e.g., ESOPs, Trackwise, BMRAM, etc.).
- Support execution method qualification/optimization of methods.
- Interface with regulatory agencies during audits as required.
- In addition to these primary duties, provide coverage for all appropriate areas.
- Contributes to assigned projects by following predefined tasks and executing as instructed.
- Perform other job duties as assigned.

Role Requirements:

2nd Shift: M-F 12pm-8pm with rotating shift weekends. Shift will be fixed according to business needs

- Bachelor's degree in biology, chemistry, biochemistry, microbiology or other related area. MS is preferred.
- At least 1 year of relevant experience in the pharmaceutical, biologics, microbiology, sterile manufacture, medical device industry or related industry.
- Thorough knowledge of microbiological and environmental monitoring, test methods is required
- 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.
- Strong written and verbal communication skills are essential.

Desired Requirements:

- Knowledge of cGMP and an understanding of the concepts of GLP, good clinical practices and FDA guidelines, applicable state and foreign regulations, and standards routinely used in the industry (i.e., ANSI, ISO, etc.) p
- Micro/Environmental knowledge to facilitate investigations is preferred
- Knowledge of LIMS systems is preferred

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

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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of

employment is expected to be between $59,000-$89,900; *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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Location
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U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
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Job Type
Full time
Employment Type
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Shift Work
No
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