Associate Expert Science & Technology

Job ID
REQ-10013825
Juli 16, 2024
USA

Zusammenfassung

Internal Job Title: Associate Expert Science & Technology- REQ-10013825 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 be assigned operational activities within the remit of the department such as clinical program support, patient safety, or OpEx. Individually contribute to and support all GxP activities in the department. Administers Quality Systems and processes (including documentation, metrics and monitoring of actions). Supports establishment of Quality operational processes. Performs routine GxP Compliance/ Operational activities according to Novartis Quality Standards. Supports Quality Projects and initiatives. Learn and grow into the next role. Under general direction, perform bioanalytical testing and other activities in functions supporting the Quality Control department. Role is a shift position.

About the Role

Your Key Responsibilities:

Your responsibilities include, but are not limited to:

- **Shift position** Shift: Tues- Friday and weekend coverage as needed 10 hour shift 10am -8pm. Shift will be fixed according to business need.
- Perform bioanalytical 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.
- Peer review and archive analytical data in lab documentation systems.
- Support monthly/quarterly laboratory cleaning.
- Manage reagent/consumable inventory and support 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.
- Follows 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.
- Knowledge of appropriate GMP/GLP quality systems (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 pre-defined tasks and executing as instructed.
- Performs other job duties as assigned.

Role Requirements:

- Bachelors degree in cell biology, immunology, molecular biology, virology, biochemistry, microbiology, or other related science.
- At least 1 year of experience in the pharmaceutical, biologics, microbiology, sterile manufacture, or medical device industry, ideally in a QC laboratory setting.
- Understanding of bioassay test methods (Elisa, flow cytometry, qPCR, cell culture) is required.
- Strong written and verbal communication skills are essential.
- Experienced in the use of computer -based systems and applications.

Desired Requirements:

- Understanding of the concepts of cGxP is preferred
- Knowledge of CAPA is preferred
- experience with Root Cause Analysis (Rca) is preferred

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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 $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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