

Expert Science & Technology - Quality Control, Information Technology

Job ID
REQ-10042039
März 11, 2025
USA

Zusammenfassung

Location: East Hanover, NJ, United States. Position will be onsite

Internal Title: Expert Science & Technology

Join Our Vision: At Novartis, we are on a transformative journey in cell and gene therapy, pushing the boundaries of medical innovation. We are currently looking for an Expert Science & Technology to join our team and help us deliver high-quality solutions that supports the management of data, analytical equipment and computerized system specialist.

Your Role: As the Expert Science & Technology you are responsible to support maintain, update and troubleshoot the GMP analytical equipments related items for Cell and Gene Therapies. Additionally, the Expert will assist with site projects such as system updates and/or enhancements within tight timelines following guidelines and compliance. Knowledge of GxP regulations is recommended.

About the Role

Key Responsibilities:

- Acts as the SME for GxP lab systems for all analytical instruments in the analytical labs in TRD CGT such as Flow cytometer, ddPCR, UPL, NGS, Empower etc.
- Ensures the GxP lab systems are in compliance to all regulatory requirements such as 21 CFR Part 11 and Annex 11.
- Day-to-day management and continuous improvement of all GxP lab systems/processes and supports data integrity initiatives related to GxP lab systems
- Works with Analytical Development and Operation teams, IT, Engineering, and Validation to support GxP lab system lifecycle management activities from concept, development, validation, implementation and maintenance to retirement.
- Authors, reviews, reports on and approves corrective actions to protocols, investigations, non-conformance, CAPAs, and other records related to GxP lab systems.
- Reviews, identifies, and leads implementation of improvements to existing lab systems. Overseas/Creates SOPs and training related to GxP lab systems.
- Lead representation of GxP lab systems during meetings. Oversees and/or communicates and tracks all follow-up items through to completion.
- Plans and leads large GxP system projects, such as LIMS implementation and lab instrument qualification. Other related duties as assigned.
- Position is a Monday-Friday, but weekend support may be needed

Requirements:

- Bachelors degree is required. A degree in Biology, Biochemistry, Molecular Biology, Immunology or related scientific discipline is preferred.
- A minimum of 3 years of industry experience in automation/digitalization projects and Pharmaceuticals.
- Experience in instrument administration preferably in CGT
- Strong knowledge of regulatory requirements and industry standards, including GxP, FDA 21 CFR Part 11, and EU Annex 11.
- Experience with validation lifecycle documentation, including URS, FRS, DS, IQ, OQ, PQ, and traceability matrices.
- Working knowledge in SQL, Java, or other LIMS programming language.
- Experienced in lifecycle management of GxP lab systems.

Desired Requirements:

- LIMS administration a plus.
- Experience working with AAV, LVV and cell therapy analytics 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 \$77,000-\$143,000; *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.

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Abteilung

Development

Business Unit

Innovative Medicines

Ort

USA

Status

New Jersey

Website

East Hanover

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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