Scientist/Principal Scientist Quality Control

Job ID
REQ-10066924

11月 14, 2025

USA

摘要

The Scientist/Principal Scientist provides technical leadership and site support for current and future Quality Control operations within Novartis which may The Scientist/Principal Scientist provides technical leadership and site support for current and future Quality Control operations within Novartis which may include analytical method lifecycle management, including method transfer, development, qualification, validation, testing, release, troubleshooting, and specification strategy. This role supports new and ongoing project support for regulatory submissions, QC operations, and cross-functional initiatives across sites.

Location: Durham #LI-Onsite

This role is located on-site in Durham, NC. Novartis is unable to offer relocation support for this role; please only apply if this location is accessible for you.

Shift: Monday-Friday, 1st - 2 positions

About the Role

Key Responsibilities:

Technical Leadership & Method Lifecycle

- Lead method development, transfer, qualification, and validation (ICH/USP/EP).
- Drive method optimization, technology scouting, and digitalization (e.g., LIMS, e-notebooks).
- Manage method control, reference standards, and critical reagent programs.

Project & Cross-Functional Support

- Collaborate with global AST, QC, site operations, QA, and Novartis stakeholders.
- Support capacity planning, lab design, equipment strategy, and procurement.
- Lead assay transfers, validations, verifications, and equipment qualifications.
- Provide technical expertise for site planning beyond GTX as a project management support

Quality & Compliance

- Author/review SOPs, URS, specifications, sampling plans, and validation protocols.
- Own and lead GMP records such as Change controls, CAPAs, investigations, etc.
- Ensure inspection readiness and alignment with quality systems.
- Lead investigations, trend analyses, and continuous improvement (Lean/Six Sigma).
- Maintain data integrity (ALCOA+), audit trails, and audit readiness.

Laboratory & Equipment Oversight

- Partner with Engineering, Facilities, EHS, and vendors for lab setup and equipment commissioning (URS, FAT/SAT/IOQ).

Regulatory & Documentation

- Support regulatory filings (IND/BLA), inspections, and responses.
- Author and approve experimental protocols, reports, and submissions.
- Represent QC/AST in cross-functional teams (CMC, Regulatory, Manufacturing).

Team Leadership & Development

- May manage FTEs or contractors across multiple projects as project needs require.
- Coach and develop staff; maintain training matrices and qualification plans.

External Collaboration

- Oversee contract testing labs to ensure project success.
- Drive supplier qualification and negotiate service agreements.

Essential Requirements

- **Education & Experience:**
  - BS in scientific discipline with 10+ years in biotech/pharma
  - MS with 8+ years or PhD with 6+ years relevant experience
  - 4+ years leadership experience preferred
- **Technical Expertise:**
  - Strong background in analytical support for biologics
  - End-to-end method lifecycle experience
  - Proficiency in techniques: HPLC/UPLC, GC, LC-MS, ICP-MS, UV-Vis, FTIR, KF, TOC, NGS, STR, AA, rcAAV, raw materials, dissolution, titration, particle size, virology, biologics, osmolality; microbiology/EM as applicable
  - Experience with lab commissioning, equipment validation, and LIMS
- **Regulatory & Quality Systems:**
  - Familiarity with cGMP/GLP, data integrity, and audit processes
  - Experience with deviations, CAPA, change control, and document management
  - Regulatory filing and agency interaction experience

Preferred:

- Six Sigma/Lean experience
- ISO 17025 familiarity
- Project management and lab startup experience

The salary for this position is expected to range between $98,700 and $183,300/year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

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.

部门
Operations

Business Unit
Quality

地点
USA

状态
North Carolina

站点
Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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