NOVARTIS

Quality Control Specialist II

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REQ-10085045
Авг. 28, 2026
США

Сводка

#LI-Onsite

Location: Morrisville, North Carolina

The QC Specialist II is a highly skilled laboratory professional who will support the start-up and growth of Novartis' Small Molecules Quality Control laboratory in Morrisville, North Carolina. This role serves as a technical subject matter expert for complex analytical techniques and instrumentation while supporting analytical testing, investigations, method transfer, validation, and data review activities within a GMP-regulated environment.

Working within a growing site organization, the QC Specialist II will support the transfer, qualification, validation, and lifecycle management of analytical methods used to test pharmaceutical raw materials, in-process materials, finished products, and stability samples. The role will also provide technical leadership in troubleshooting, analytical investigations, equipment qualification, and training activities while partnering across Quality, Manufacturing, MS&T, Engineering, and Validation teams.

This is an exciting opportunity to help build the technical capabilities, laboratory systems, and quality infrastructure required to support the continued growth of the Morrisville manufacturing site.

About the Role

Key Responsibilities

- Serve as a subject matter expert for complex analytical techniques and instrumentation, including HPLC, UPLC, GC, LC-MS, ICP spectroscopy, dissolution, spectroscopy, and physicochemical testing.
- Perform and troubleshoot chromatographic and wet-chemistry testing of raw materials, in-process materials, finished products, and stability samples in compliance with GLP and cGMP requirements.
- Manage analytical method transfers, validation, troubleshooting, risk mitigation, and lifecycle-management activities to support the Morrisville Quality Control laboratory.
- Lead and support OOS and deviation investigations, including root-cause analysis, CAPA definition, issue resolution, and KPI/KQI trending.
- Review and approve chromatographic and non-chromatographic data and analytical tests, ensuring data integrity, accuracy, and readiness for analytical release.
- Provide expert support for laboratory equipment and system qualification and validation, including user requirements specifications, functional specifications, IQ/OQ/PQ activities, calibration, maintenance, and qualification-plan preparation.
- Develop and deliver site training for Empower CDS, complex analytical technologies, laboratory processes, and applicable quality requirements.
- Ensure activities comply with GxP, ALCOA+ data-integrity principles, regulatory requirements, and Novartis policies while collaborating across QA, QC, MS&T, Engineering, Operations, and other site functions.

Essential Requirements

- Bachelor's, Master's, or PhD in Chemistry, Analytical Chemistry, Pharmaceutical Sciences, or a related scientific discipline, with working experience in technical drug development, manufacturing, analytics, or quality within a cGMP-regulated environment.
- Hands-on experience with HPLC, GC, UPLC, and/or LC-MS analysis, including experience with analytical method validation and transfer; experience with LabWare LIMS and Empower CDS is preferred.
- Proven experience in analytical method development, validation, transfer, troubleshooting, and lifecycle management.
- Strong technical knowledge of complex analytical techniques, such as HPLC, UPLC, GC, ICP, dissolution, LC-MS, spectroscopy, and physicochemical testing.
- Good understanding of GxP, ALCOA+ data-integrity principles, ICH Q2, ICH Q10, ICH Q14, and relevant FDA, EMA, and other regulatory expectations.
- Broad knowledge of cGMP requirements and experience working within technical drug development, manufacturing, analytical, or quality operations.

Desirable Requirement

- Prior experience developing and delivering technical training related to analytical instrumentation, laboratory systems, or quality control processes.

The salary for this position is expected to range between $89,600 - $166,400 per 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.

To learn more about the culture, rewards and benefits we offer our people clickhere.

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: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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.

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