NOVARTIS

Quality Control Specialist II

Job ID
REQ-10085045
Aug 28, 2026
LOC_US

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 click here.

Role Requirements

Division
DIV_TO
Business Unit
General Management
Location
LOC_US
Site
Morrisville
Company / Legal Entity
U473 (FCRS = US473) Novartis Innovative Technologies Inc
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID
REQ-10085045

Quality Control Specialist II

Apply to Job

Source URL: *https://jobapi.novartis.com/req-10085045-quality-control-specialist-ii*

List of links present in page

1. https://jobapi.novartis.com/req-10085045-quality-control-specialist-ii
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Morrisville/Quality-Control-Specialist-II_REQ-10085045
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Morrisville/Quality-Control-Specialist-II_REQ-10085045