NOVARTIS

Quality Control Specialist II

Job ID
REQ-10085045

八月 28, 2026

USA

摘要

#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 click here.

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.

部门
Operations

Business Unit
General Management

地点
USA

状态
North Carolina

站点
Morrisville

Company / Legal Entity
U473 (FCRS = US473) Novartis Innovative Technologies Inc

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6af25b20cf6c4631242050", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop: false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: kPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if (kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if (kPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", // Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default: alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable: true }; } if (kPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (kPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {}; config.plugins.googleTagManager.customEventsTracking = {}; config.plugins.googleTagManager.containerId = 'GTM-57RJQ5'; config.plugins.googleTagManager.customEventsTracking.custom = []; config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents: false, playlistEvents: false, castEvents: false } }; }
```

```
// Ensure the global player registry array always exists, regardless of embed type. window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise = thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbnailEmbed() returns a Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to capture the player directly. thumbEmbedPromise .then(function(player) { window.kalturaPlayerVideos.push(player); // Notify kaltura datalayer.js that a new player is ready so it can // attach custom event listeners immediately, regardless of when // the user clicked the thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', { detail: { player: player } })); }) .catch(function(error) { console.error(error); }); } catch (e) { console.error(e.message) }
```

Job ID
REQ-10085045

Quality Control Specialist II

Apply to Job



Job ID
REQ-10085045

Quality Control Specialist II

Apply to Job

Source URL:
https://prod1.novartis.com.cn/careers/career-search/job/details/req-10085045-quality-control-specialist-ii

List of links present in page

1. https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf
4. mailto:us.reasonableaccommodations@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Morrisville/Quality-Control-Specialist-IIREQ-10085045
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Morrisville/Quality-Control-Specialist-IIREQ-10085045