

AS&T Specialist

Job ID
REQ-10085042

8月 28, 2026

USA

摘要

#LI-Onsite

Location: Morrisville, North Carolina

The AS&T Specialist will play a critical role in supporting the start-up and growth of Novartis' Small Molecules Quality Control laboratory in Morrisville, North Carolina. This position provides scientific analytical support across method validation, method transfer, analytical troubleshooting, equipment qualification, and commercial testing activities while ensuring the highest standards of quality, compliance, and data integrity.

Working within a growing site organization, the AS&T Specialist will support the implementation and lifecycle management of analytical methods, technologies, and laboratory equipment used to test pharmaceutical raw materials, intermediates, and finished products. The role will contribute to equipment qualification, calibration, maintenance, and technology implementation activities while partnering with cross-functional teams to support product transfers and laboratory readiness.

This is an exciting opportunity to help build the analytical capabilities and laboratory infrastructure

supporting the future growth of the Morrisville manufacturing site.

About the Role

Key Responsibilities

- Execute analytical method validation, transfer, optimization, and lifecycle management activities supporting pharmaceutical raw materials, intermediates, and finished products.
- Provide scientific and technical support for analytical investigations, including OOS results, deviations, root cause analysis, troubleshooting activities, and CAPA development.
- Serve as a technical owner for analytical laboratory equipment, coordinating qualification, calibration, maintenance, lifecycle management, and performance monitoring activities to ensure reliable and compliant laboratory operations.
- Lead equipment qualification and implementation activities, including qualification planning, computerized system validation (CSV) support, introduction of new analytical technologies, and readiness activities associated with laboratory start-up and expansion.
- Perform and support complex analytical testing utilizing technologies such as HPLC, UPLC, GC, LC-MS, ICP spectroscopy, dissolution, and physicochemical testing techniques.
- Author, review, and maintain analytical documentation, including protocols, reports, specifications, SOPs, investigations, qualification documentation, and technical records in accordance with GxP requirements.
- Support product transfers, validation programs, and implementation of new analytical methods and technologies required to advance the Morrisville site and future manufacturing operations.
- Ensure compliance with cGxP, data integrity, regulatory, and Novartis quality standards while supporting audits, inspections, commercial release testing, and continuous improvement initiatives.

Essential Requirements

- Bachelor's degree in Chemistry, Pharmacy, Microbiology, or another related scientific discipline with a minimum of 5 years of experience working in a cGMP laboratory environment supporting pharmaceutical or biotechnology operations.
- Hands-on experience with complex analytical techniques and instrumentation, including HPLC, UPLC, GC, LC-MS, ICP spectroscopy, dissolution, and/or physicochemical testing.
- Experience using LabWare LIMS and familiarity with building methods and utilizing Empower CDS.
- Working knowledge of ICH Q2, ICH Q7, ICH Q10, GxP requirements, data integrity principles, and good documentation practices.
- Demonstrated ability to troubleshoot analytical methods and laboratory instrumentation while supporting compliant laboratory operations and scientific investigations.
- Strong communication, collaboration, and problem-solving skills, with the ability to identify key issues, adapt to changing priorities, and work effectively across cross-functional teams.

The salary for this position is expected to range between \$89,600 and \$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 \(PDF 30 MB\)](#)

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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 Gene Therapies

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
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"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"]) {
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config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation =
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(kPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {};
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config.plugins.googleTagManager.containerId = 'GTM-57RJQ5';
config.plugins.googleTagManager.customEventsTracking.custom = [];
config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents:
```

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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) }
```

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