

Head, Quality Control

Job ID
REQ-10070119

3月 01, 2026

USA

摘要

At Novartis, we're reimagining medicine – and quality is at the center of everything we do.

We're seeking an experienced Head of Quality Control (Associate Director Level) to provide strategic and operational leadership for QC laboratories supporting Drug Substance, Drug Product, and Finished Product manufacturing, including packaging operations. This role is responsible for designing and implementing robust, compliant testing strategies that ensure cGxP adherence to U.S. and EU regulations while building a scalable QC organization capable of supporting clinical and commercial manufacturing.

This is a senior, hands-on leadership role with full accountability for QC strategy, compliance, and inspection readiness across clinical and commercial operations.

About the Role

#LI-Onsite

Location: Durham, NC

This role is on-site 5 days a week and does not have the ability to work remotely. This role is located in Durham, NC and will eventually move to Morrisville, NC at a later date

Key Responsibilities:

- Develops and executes corporate quality policies, practices, procedures, standards, and systems necessary to ensure adherence to DS/DP/FP production and product management in accordance with the cGxP compliance to U.S. and EU regulations.
- Oversees the testing and validation strategy, with a concentrated focus on method verification and validation.
- Maintains a robust Environmental Monitoring program that meets U.S./EU and other applicable regulatory requirements.
- Organizes and directs cross functional relationships with Manufacturing, Engineering, MS&T, Quality Assurance, and Regulatory.
- Build, lead, and develop QC laboratory teams by hiring and mentoring staff, setting performance expectations, manage external contract vendors, and ensuring efficient utilization of laboratory resources.
- Authors and approve documents required for regulatory submissions.
- Develops, implements, and ensures laboratory procedures and policies are followed.
- Provides presentations, explain laboratory qualification and operations, and defend testing results during FDA and other inspections.
- Other duties for which QC is responsible, as assigned.

Essential Requirements:

- BS or MS in Chemistry, Pharmacy, or a related natural science with a minimum of 10 years of experience in a cGMP laboratory environment; PhD in life sciences preferred.
- Deep working knowledge of U.S. and EU regulatory requirements, including USP and European Pharmacopoeia standards.
- Minimum of 6 years of people and laboratory management experience.
- Prior proven experience leading operational quality control organizations.
- Demonstrated experience establishing startup lab facilities supporting clinical and/or commercial manufacturing.
- Direct experience supporting and leading regulatory agency inspections.
- Fluency in English (written and verbal)

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$138,600 and \$257,400/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: 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
Production / Manufacturing

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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function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =
document.getElementById("kalturaplayer69bb71df22b69260818461"); var mediaContainer =
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =
parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles
of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var
finalWidth = parseFloat(parentStyles.width); if (finalWidth <= 0) var config = { targetId:
"kalturaplayer69bb71df22b69260818461", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false,
allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: {
disable: true }, "playkit-js-transcript":{ position: "right", // Default: bottom;( ' left ', ' right', ' top ', 'bottom ' ) to
enable transcript. expandMode: "over", // Default: alongside;( ' alongside', ' hidden ', 'over ' )
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expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable: true } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: KalturaPlayer.ui.components.Remove } ] } }; config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true }; config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true }; config.ui.uiComponents = []; 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 } };
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try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other media. kalturaPlayer.loadMedia({entryId: "1_dgfvmafo"}); setTimeout(() => { setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) { players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => { players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause === 'function') { otherPlayer.pause(); } })); }); }); } catch (e) { console.error(e.message) }
```



VIDEO

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