

Specialist, Clinical Manufacturing

Job ID
REQ-10075401

6月 25, 2026

USA

摘要

#LI-Onsite

Location: Durham, NC

Relocation Support: This role is based in Durham, NC. Novartis is unable to offer relocation support: please only apply if accessible.

NOTE: This role is typically Monday-Friday working standard business hours. However, during active clinical campaigns, working overtime, nights, and weekends will be required.

If you're energized by seeing new clinical therapies move from idea to execution, this is your opportunity to make a visible impact. As a Specialist, Clinical Manufacturing, you will play a hands-on role at the heart of manufacturing execution, introducing new clinical products into a Good Manufacturing Practice environment. Working closely with Manufacturing, Manufacturing Science and Technology, Engineering, and Technical Research and Development, you'll translate technical knowledge into compliant, real-world manufacturing outcomes. This role offers a unique blend of shop-floor presence, technical authorship, and project ownership—giving you direct visibility into how

your expertise enables safe, timely delivery of medicines that matter.

About the Role

Key Responsibilities

- Responsible for implementation of new clinical products into the facility, ensuring safe, compliant, and timely execution.
- Provide hands-on, front-line manufacturing support during clinical batch execution with shift teams.
- Author and manage master manufacturing documents of assigned products, including Master Batch Record, Standard Operating Procedure, Bill of Material (BOM), and Recipe, Quality Risk Assessment, and Hazard Analysis.
- Support technology transfer projects, including new product change controls.
- Manage projects implementing significant improvements to clinical manufacturing processes.
- Partner cross-functionally with the PMO group, Manufacturing, Manufacturing Science and Technology, Engineering, and Technical Research and Development teams.
- Support deviations, corrective actions, and internal or external audits for group owned processes.

Essential Requirements

- Bachelor ' s degree in Engineering or Life Sciences and five years of experience in biopharmaceutical based GMP manufacturing operations.
- Hands-on experience in technology transfer of biotechnology candidate clinical products and/or technology transfer of commercial products from site to site.
- Strong technical writing ability required. Excellent oral and written communication skills.
- In-depth knowledge of Food and Drug Administration regulations and Good Manufacturing Practice systems.
- Applied knowledge of Quality by Design, six-sigma, and operational excellence tools in creating efficient and high-quality processes and end products.
- Ability to travel to other internal sites, vendors, and contract manufacturing organizations, as required, typically less than five percent.

The salary for this position is expected to range between \$41.05 and \$76.25 per hour. 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:

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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

Production / Manufacturing

地点

USA

状态

North Carolina

站点

Durham

Company / Legal Entity

U473 (FCRS = US473) Novartis Gene Therapies

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kaltura\player6a3ddde123750508734436", provider: { widgetId: "1Qm7rm1pm", 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 kalturaPlayer =
kPlayer.setup(config); // Add the player to the global array.
window.kalturaPlayerVideos.push(kalturaPlayer); // Load the Player for other media.
kalturaPlayer.loadMedia({entryId: "1_dgfvmafo"}); } catch (e) { console.error(e.message) }
```

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