

Senior Specialist, Manufacturing Technical Support

Job ID
REQ-10083853

7月 29, 2026

USA

Available in: English

摘要

Imagine being the go-to expert who helps bring life-changing medicines to patients without interruption. As a Senior Specialist, Manufacturing Technical Support, you will play a critical role at the heart of our manufacturing operations, partnering closely with production teams to ensure every batch is delivered safely, efficiently, and in full compliance with quality standards. This is an opportunity to apply your technical expertise, drive continuous process improvements, solve complex manufacturing challenges, and influence the performance of innovative biopharmaceutical products in a highly regulated environment. Your work will directly contribute to operational excellence and our mission to reimagine medicine for patients around the world.

About the Role

Location:

- This position will be located in Durham, NC and will be an onsite role.
- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Provide frontline technical support to manufacturing teams to ensure safe, compliant, and on-time batch execution.
- Serve as the SME for assigned products and processes, driving technical excellence and process knowledge.
- Review and maintain master manufacturing documents, including MBRs, BOMs, and manufacturing recipes.
- Monitor critical process parameters and ensure compliance with approved manufacturing instructions and quality requirements.
- Lead and support manufacturing investigations, root cause analyses, and timely CAPA implementation.
- Assess technical changes and ensure execution through established change control procedures.
- Develop, review, and continuously improve manufacturing SOPs and electronic batch records.
- Support ongoing process verification through data analysis, product performance monitoring, and CAPA effectiveness tracking.
- Perform technical assessments and resolution of process-related issues, including deviations, complaints, OOS, and OOE events.
- Lead or support process validations, technology transfers, new technology implementation, and continuous improvement initiatives while maintaining GMP inspection readiness.

Essential Requirements:

- Bachelor's degree in Engineering or Life Sciences with 7+ years of experience in biopharmaceutical GMP manufacturing operations.
- Demonstrated experience developing, revising, and maintaining manufacturing documentation in a regulated environment.
- Proven experience investigating complex manufacturing deviations and driving timely CAPA implementation.
- Strong knowledge of FDA regulations, GMP requirements, and quality management systems.
- Experience providing technical process support within a pharmaceutical or biotechnology manufacturing facility.
- Working knowledge of Quality by Design (QbD) principles, Six Sigma methodologies, and operational excellence tools.
- Excellent written and verbal communication skills with strong technical writing capabilities.
- Ability to travel up to 20% to support activities at internal sites, vendor locations, and CMOs.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$108,500 and \$201,500 annually

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.

#LI-Onsite

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

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6a6aa9d417748728488983", 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 } }; }

```

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// 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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