NOVARTIS

CMC Facilitator

Job ID
REQ-10092119

十一月 17, 2026

USA

摘要

Join Novartis and play a critical role in bringing innovative medicines to patients worldwide. As a CMC Facilitator, you will serve as a key partner across Regulatory Affairs, Quality, Manufacturing, and Technical Operations, helping drive regulatory strategy and product lifecycle activities in a GMP environment. This is an opportunity to influence global submissions, support complex change initiatives, and collaborate with cross-functional teams to ensure compliance while accelerating patient access to life-changing therapies.

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:

- Lead CMC regulatory activities supporting product development, commercialization, and lifecycle management.
- Assess manufacturing, process, analytical, and quality changes for global regulatory impact.
- Develop regulatory strategies supporting post-approval changes and submission readiness.
- Author, review, and coordinate CMC regulatory documentation for global submissions.
- Support preparation of CTD Module 3 content and related technical documentation.
- Partner with Quality, Manufacturing, Technical Operations, and Regulatory Affairs stakeholders.
- Coordinate responses to Health Authority inquiries and regulatory commitments.
- Monitor evolving global regulatory requirements and assess impact to marketed products.
- Drive cross-functional alignment to ensure compliance, execution, and timely regulatory outcomes.
- Support inspection readiness and adherence to GMP and applicable regulatory requirements.

Essential Requirements:

- Bachelor ' s degree in Life Sciences, Pharmacy, Chemistry, Engineering, or related discipline.
- 5+ years of experience in Regulatory Affairs, CMC, Quality, Manufacturing, or Technical Operations.
- Experience supporting global regulatory submissions and product lifecycle management activities.
- Working knowledge of FDA, ICH, and global CMC regulatory requirements.
- Experience assessing regulatory impact of manufacturing, process, analytical, or quality changes.
- Ability to author, review, and coordinate technical regulatory documentation and submissions.
- Strong cross-functional collaboration skills within GMP-regulated pharmaceutical environments.
- Proven project management skills with the ability to manage multiple priorities simultaneously.

Desirable Requirements

- Experience supporting global regulatory strategies across multiple regions and Health Authorities.
- Experience working with international cross-functional teams and global product portfolios.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $89,600.00 and $166,400.00 USD 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
Quality

地点
USA

状态
North Carolina

站点
Durham

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

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6afc9ff8e7c89239273088", 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 kalturadatalayer.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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