

QA Compliance Expert - Regulatory CMC Facilitator

Job ID
REQ-10087109

九月 23, 2026

India

摘要

#LI-Hybrid

Location: Hyderabad, India

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

Join Novartis and play a pivotal role in ensuring patients worldwide receive medicines without interruption. As a QA Compliance Expert - Regulatory CMC Facilitator, you will be at the center of regulatory compliance and product lifecycle management, partnering with global stakeholders to navigate complex Chemistry, Manufacturing and Control requirements. This is an exciting opportunity to influence strategic decisions, drive regulatory excellence, and support high-quality product delivery while working in a collaborative, international environment where your expertise can make a meaningful impact every day.

About the Role

Key Responsibilities

- Partner with regulatory teams to align Chemistry, Manufacturing and Control strategies across the product lifecycle.
- Evaluate product changes for regulatory impact and support compliant change control decisions.
- Serve as the primary site contact for regulatory matters and cross-functional stakeholder engagement.
- Provide regulatory guidance during quality events, investigations, escalations, and compliance discussions.
- Coordinate timely reviews of Chemistry, Manufacturing and Control documentation for assigned products.
- Support regulatory inspections and audits by identifying and addressing compliance risks.
- Drive initiatives that strengthen regulatory compliance and promote process harmonization.
- Deliver training and knowledge sharing to enhance regulatory awareness across site functions.

Essential Requirements

- Advanced degree in Chemistry, Biology, Pharmacy, Engineering, or a related scientific discipline.
- More than three years of experience in a Good Practice regulated environment.
- Experience in Quality Assurance, Manufacturing, Development, or Regulatory Affairs within the pharmaceutical industry.
- Strong knowledge of biologic drug substance manufacturing processes involving recombinant proteins or nucleic acids.
- Ability to work independently, manage complex priorities, and make sound quality decisions.
- Fluent English communication skills with the ability to collaborate across global teams.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

You'll receive You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

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 \(PDF 30 MB\)](#)

部门

Operations

Business Unit

Other

地点

India

站点

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

```

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6abb0c397fa62725258666", 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 } }; }

```

```

// 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) }

```

Accessibility and accommodation

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Job ID
REQ-10087109

QA Compliance Expert - Regulatory CMC Facilitator

[Apply to Job](#)



Job ID
REQ-10087109

QA Compliance Expert - Regulatory CMC Facilitator

[Apply to Job](#)

Source URL:

<https://prod1.novartis.com.cn/careers/career-search/job/details/req-10087109-qa-compliance-expert-regulatory-cmc-facilitator>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
3. <mailto:diversityandincl.india@novartis.com>
4. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/QA-Compliance-Expert---Regulatory-CMC-FacilitatorREQ-10087109-1>
5. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/QA-Compliance-Expert---Regulatory-CMC-FacilitatorREQ-10087109-1>