NOVARTIS

Global Regulatory Manager, GRSS&C

Job ID
REQ-10089484

十一月 23, 2026

India

摘要

Responsible for managing regulatory clinical trials or maintenance activities independently. The GRM focuses on the delivery of regulatory activities related to clinical trial applications or to the maintenance of the assigned portfolio for selected countries/region.

The GRM-RACS collaborates with the study team or with the Country lead and the line functions to ensures high quality (complete, well organized, scientifically accurate, compliant) submissions are prepared, reviewed and timely approved.

About the Role

Key Responsibilities:

- For a product portfolio, the aGRM- RACS ensures under supervision that clinical trial applications or maintenance submissions are prepared on time and in compliance with

regulatory regulations, guidelines, and in line with Novartis processes and system requirements.
- Manage assigned product portfolio and country / region knowledge.
- Use regulatory expertise and knowledge to identify issues, gaps, and tradeoffs to avoid/minimize delays and achieve timely submission and approvals.
- Manage timely responses to HA queries and collaborate with regulatory lead to preparing strong justifications to address regulatory gaps.
- Responsible for appropriate entering of product specific attributes in compliance database and applicable RIMs.
- Facilitate preparation and finalization of documents for HA interactions for matters of low complexity.
- Contribute to non-project related initiatives focused on productivity, continuous improvement, and automation.
- Share knowledge on specific topics and support other associates within Regulatory Affairs.

Minimum Requirement

- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph D, PharmD) preferred.
- Regulatory affairs experience of 9 to 13 (at least 7 years of relevant exp) with knowledge of regulations, guidelines and regulatory processes for maintenance activities
- Experience of regulatory submission and approval processes in major countries. Planning, execution, reporting, regulatory review, compliance and submission experience
- Ability to participate in process improvements, simplification, automatization and operational excellence initiatives
- Understand safety and efficacy data and product labels. Reliable, timely, accurate and proactive communication as appropriate
- Basic organizational awareness (e.g., interrelationship of departments). Experience in a global/matrix environment or cross- functional teams in the pharmaceutical industry

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
Development

Business Unit
Development

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6b089fd80a20d932723218", 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 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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