RA CMC Submission Coordinator

Job ID
REQ-10071286

2月 05, 2026

India

摘要

Deliver accurate, compliant, and on-time Regulatory CMC operations, compliance, and project management activities, maintaining eCTD readiness, and stewarding data/documents in RIMS/DMS per established procedures. Manage multiple tasks simultaneously, and consistently apply a structured, process - oriented approach. Strong communication skills and a high level of digital and data fluency including familiarity with AI - enabled tools and emerging IT technologies.

About the Role

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Help deliver accurate, compliant, on-time CMC submissions that keep studies moving and products available for patients. This role is ideal for a detail-driven professional who values structured processes and wants to build depth in CMC submission coordination, centralization of regulatory activities, and in data and digital tools.

Key Responsibilities:

- Perform compliance and operational activities including CMC submission QC check, Document Format checks and IND annual report writing. CMC contact for some countries and compliance/ regulatory database entry and reports
- Create CMC submission documentation such as folders structure, metadata, RA request forms and act as data stewards in the applicable Regulatory Information and Documentation Management System
- Ensure CMC documentation is eCTD compliant, eCTD filenames assigned, Document formatting (DA) checked, PDF properties are compliant for eCTD submission, documentation is finalized and eCTD file names assigned
- Coordinate data/KPIs required for reports within RA CMC
- Support project teams for document finalization, collate ancillary documents requirements from various sources (e.g. databases, OneNote, trending etc.) and support coordination and management through the appropriate system
- Coordinate, prepare and track CMC submissions for delivery to RA Publishing
- Perform super-user role of RA CMC documentation system/ support super-user for e.g. account requests/ ticket generation/ modifications as assigned
- Acquire and maintain GMP Certificates and Manufacturing Authorizations required for RA CMC submission in the Document Management System
- Support other team members for end-to-end submission coordination

Essential Requirements

- For Master ' s in Pharmacy: Minimum 2 years of regulatory experience in Regulatory CMC operations, compliance, and project management. Internship experience during the degree program is not counted.
- For Other Scientific Master ' s Degrees: Minimum 3 years of regulatory experience in Regulatory CMC operations, compliance, and project management. Internship experience during the degree program is not counted.
- Experience with: Pharmaceutical industry documentation systems, Regulatory Information Management Systems (RIMS), Data standards, data systems and data management tools
- Proven ability to work effectively with global, cross functional project teams
- Strong planning, organizational, and interpersonal skills
- Demonstrated ability to manage multiple priorities simultaneously (multitasking is essential)
- High level of computer literacy and competency with data driven and IT systems; strong data processing skills
- High level of digital and data fluency including familiarity with AI - enabled tools and emerging IT technologies.

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.

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

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

function adjustKalturaPlayer() { var deviceWidth = window.innerWidth || document.documentElement.clientWidth || document.body.clientWidth; var mediaElement = document.getElementById("kalturaplayer698466f2529e8701512241"); var mediaContainer = mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px"; var originalWidthValue = parseFloat(originalWidth); var originalHeightValue = parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var finalWidth = parseFloat(parentStyles.width); if (finalWidth var config = { targetId: "kalturaplayer698466f2529e8701512241", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: { disable: true }, "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 } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [{ presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: KalturaPlayer.ui.components.Remove }] } }; config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true }; config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true }; config.ui.uiComponents = []; 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 } };

try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other media. kalturaPlayer.loadMedia({entryId: "1dgfvmafo"}); setTimeout(() => { setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) { players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => { players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause === 'function') { otherPlayer.pause(); } }); }); } } catch (e) { console.error(e.message) }

VIDEO

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

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