NOVARTIS

Product Lead, RA Platform Operations

Job ID
REQ-10076255

4月 24, 2026

India

摘要

As a member of the RA Platform Operations team, the Product Lead will play a pivotal role in enhancing the organization's operational efficiency and technological advancement. This position can support one or several Capabilities which are underlying the Platform: Release Management, Validation, Migration, and Business Administration.
The Platform Operations Product Lead supports the Platform in seamlessly managing Release, Validation, Migration and/or Business Administration activities across all Data & Technology Products, thereby minimizing disruptions to business operations. This role impacts the organization's ability to meet business needs and technical standards, ensuring the continuity and reliability of the Regulatory Affairs Technology infrastructure.

About the Role

Major Accountabilities:

- Ensure the Capability is fit for purpose (incl. related processes such as SOPs, WIs, etc.) and achieves the desired business value and impact o Support the identification, assessment, and management of risks associated with release activities. Support the development of contingency plans to address potential issues and ensure minimal disruption to business operations o Support resolution of Release/Validation/Migration/Business Administration issues Support Release/Validation/Migration activities in the context of new releases across Products, to ensure compliance with regulatory and industry standards within the life sciences sector o Report on key performance indicators (KPIs) to measure the effectiveness of the processes covered by the Capability. Regularly track and report on these metrics to identify areas for improvement and demonstrate the value of the capability team.
- Release Management responsibilities o Support the end-to-end release lifecycle, from planning through to deployment and post-deployment support.
- Validation responsibilities: Support and implement validation frameworks/standards to ensure compliance with GxP, 21 CFR Part 11, GCP ICH E6, and FDA Electronic Source Data in Clinical Investigations (amongst others), including but not limited to: Validation Plan, User Requirements Specification (URS), Functional Requirements Specification (FRS), Risk Assessment, Operational Qualification (OQ), Performance Qualification (PQ), Traceability Matrix, etc.
- Migration responsibilities o Support and implement migration frameworks/standards, and manage/execute migration projects, ensuring a seamless transition and integration of new Systems, Data and Products with minimal disruption to business, including but not limited to: Migration Plan, Data Mapping, Data Extraction Scripts, Data Cleansing Reports, Transformation Logic, Migration Scripts/Programs, etc.
- Business Administration responsibilities: o Ensure access control, security management, and continuous operation and availability of technology products Act as the first-level support for business administration issues; implement and follow a harmonized approach across all technology products o Collaborate closely with IT to ensure optimal systems performance and availability, assisting in the identification and troubleshooting of any issues that may arise o Support and implement business administration strategies and frameworks/standards to ensure compliance for the management of technology operations, focusing on efficiency and effectiveness including but not limited to: Governance Framework, Compliance & Regulatory Documentation, Risk Management Plan, User Account Management Procedures, Access Control Policies, Audit and Review Reports, Data Security Plan, etc. - as needed/relevant
- Stakeholder Engagement: o Support continuous expansion of knowledge and the adoption of a digital mindset within Regulatory Affairs o Support change management strategies to ensure smooth adoption of technology initiatives, at the Capability level
- Collaboration and Partnerships: o Collaborate closely with cross-functional teams to ensure that above initiatives meet business goals, program timelines, and budgets. Facilitate regular update meetings to track progress, address issues promptly, and keep all stakeholders informed. o Support vendor oversight at the capability level, across product(s), in collaboration with IT and the External Partnerships Teams
- Quality and Compliance: o Deliver with the required quality and in a compliant way, on above activities for the assigned Product(s)/Service(s), aligned with the NVS Quality Manual o Ensure that Security and Compliance policies and procedures are within the scope of the Capability and prepare for audit readiness and inspection requirements (incl. Related mitigations or actions triggered by audits & inspections).
- Project and Program Support: o Support assigned projects and programs impacting the Capability and/or underlying Service(s)/Product(s), through timely delivery of high-quality milestones in alignment with business requirements
- Demand Management: o Re-direct/raise demand(s) for technology services and operational

support related to business administration activities, arising from the Capability or from various functions within Regulatory Affairs

Minimum Requirements:

- Minimum 5+ years of relevant industry experience. Minimum 3+ years in cross-functional matrix organization. Understanding and direct relevant experience with the Release Management, Validation, Data Migration, and/or Business Administration landscape of pharmaceutical regulatory affairs (including Veeva RIM, eCTD and Power Apps)
- Knowledge of drug development process as well as international drug registration and approval, of regulatory business processes and regulatory information management
- Hands-on experience in technology process requirements. Problem-solving skills and seeking clarity in ambiguous situations. Excellent verbal and written communication skills. Broad experience in quality assurance/compliance, computer system validation within the pharmaceutical/biotech arena, and knowledge of relevant regulatory requirements
- Experience in Release Management, Validation, Migration and/or Business Administration activities

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 config = { targetId: "kalturaplayer69fc62c4bef4a198883690", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: {}, sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, css : "/modules/custom/arcticnckalturaaddon/css/kalturavideo.css", components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [{ presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: KalturaPlayer.ui.components.Remove }] } }; // Check and add plugins only if they exist if (KalturaPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if (KalturaPlayer.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 (KalturaPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (KalturaPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (KalturaPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (KalturaPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (KalturaPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (KalturaPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (KalturaPlayer.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 } }; }

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"}); } 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-10076255

Product Lead, RA Platform Operations

Apply to Job

Job ID
REQ-10076255

Product Lead, RA Platform Operations

Apply to Job

Source URL:
https://prod1.novartis.com.cn/careers/career-search/job/details/req-10076255-product-lead-ra-platform-operations

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/Product-Lead--RA-Platform-OperationsREQ-10076255-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Product-Lead--RA-Platform-OperationsREQ-10076255-1