External Vigilance Engagements Lead

Job ID
REQ-10088191

九月 25, 2026

India

摘要

Provide expertise and cross functional leadership on pharmacovigilance and/or device vigilance for all assigned Novartis Enterprise contractual arrangements including Global and Local Vigilance Agreements, and Clinical Trial Supply Agreements; and the management of transition of vigilance systems and processes (including for medical devices, and diagnostic portfolios) as part of Mer-gers & Acquisitions, divestments, in and out-licensing and other global strategic projects. Negoti-ate and maintain vigilance agreements with external business partners, managing these alliances, including oversight of compliance, and acting as key contact person for Development, PS&PV and external customers.

About the Role

Major Accountabilities

- Expertise - Maintain knowledge of current and developing regulations/guidelines for

pharmacovigilance and/or device vigilance and provide expertise and advice to all concerned Novartis line-units and external partners for Novartis Enterprise contractual arrangements and Development Integration teams (Transitions), if applicable.

- Strategy/VAP Risk Assessment (VAPRA) - take part in VAPRA activities for new deals as required to assess potential partner ' s PV systems for the impact on the Novartis Enterprise.
- Negotiation and Alliance Management- Manage assigned vigilance agreements with external business partners by leading negotiations to define conditions of the agreement, *guided by the EVE Director/EVE Associate Director.* Ensure regular contact with key customers to facilitate agreement compliance and good relations and acting as key contact person for external and internal stakeholders to identify needs and address resolution of issues. Initiate appropriate updates to vigilance agreements in a timely manner; support Head EVE / EVE Director to ensure that vigilance agreements are implemented as required to maintain regulatory compliance and Development PS&PV standards. Ensure accuracy and up-to-date information of agreements in the vigilance agreement repository.
- Lead assigned transition projects in PS&PV, which are of high priority/criticality to the business, by implementing the strategy defined in alignment with the Development Integration strategy and assembling the appropriate teams and supervising/directing their work. Escalate to the line function managers as appropriate any potential disruption of the project plan in a timely manner to avoid delays/failures in transition project deliverables. Maintain the project team's awareness of strategic changes in project goals, status, and milestones at all times, as communicated by the Head EVE/ EVE Director.
- Regulatory and Partner Compliance - communicate requirements to PS&PV functions and external line-units to ensure compliance with vigilance agreements and with transition project plan as required; with Head EVE / EVE Director and Compliance Team, ensure external business partners and PS&PV management are alerted to compliance and reconciliation issues and have oversight of corrective actions and their effectiveness to improve and maintain a high level of compliance.
- Training and communication - Assist in the development, maintenance and training Novartis PS&PV and other concerned departments on worldwide Novartis pharmacovigilance standards & procedures for pharmacovigilance agreements, using internal guidelines, tools and templates.
- Represent External Vigilance Engagements in internal and external meetings as needed, *guided by EVE Director/EVE Associate Director as required.*
- Audits and Inspections: support internal Novartis and VAP audits, Novartis audits of VAPs, VAP regulatory inspections, Novartis regulatory inspections, including those covering transition projects

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Essential Requirement

- Degree in Biomedical Science or related scientific discipline. Higher degree desirable.
- Minimum 2 - 5 years ' experience in clinical safety/ (pharmaco)vigilance or in a regulatory/compliance related area including a thorough knowledge of the functional requirements of clinical safety reporting and a clinical safety database. Good current knowledge of industry regulations and guidelines in the field of Pharmacovigilance and/or device vigilance.
- Experience in Clinical Trial Safety preferable. Candidates should have knowledge of clinical safety-reporting requirements, safety databases and relevant industry regulations. Clinical trial safety experience is preferred, while experience with vigilance agreements, partner

management or transition projects would be advantageous.

- Strong interpersonal communication skills and negotiation/problem solving skills
- Experience and ability to work in matrix cross-functional environments

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: "kalturaplayer6abbe7beb2270568746457", 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) }

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