

Regulatory Affairs Manager

Job ID
REQ-10077683

6月 22, 2026

Vietnam

Available in: English

摘要

Ensure of regulatory compliance and achieving registration licenses on time from local authority, in line with company 's objectives.

Location: Ha Noi

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

About the Role

Key Responsibilities

- Ensure of assigned registration submission and approval on time (new registration, renewal registration, variations including new site), in line with local commercial strategies.

- Ensure regulatory compliance for a sustainable life-cycle management: safety label change, labeling, CMC, PSUR and other MA lifecycle support are performed in accordance with local regulations and relevant Novartis SOPs
- Coordinate with QA/Supply chain departments to support for product 's availability on market.
- Collaborate with commercial team for launching preparation, tender management and promotional material management.
- Ensure of regulatory database updated (DRAGON, REDI, RA Shared documents ...)
- Develop and maintain effective working relationships with Drug Administration of Vietnam and key Stakeholders to support current and future business activities (which are under responsibility of Regulatory Affairs).
- Proactively involve on shaping regulation as assignment by time.
- Ensure compliance to current local regulations: Awareness of current and new local regulations. Interpretation and communication of any changes that may impact Novartis in a timely manner to all relevant Stakeholders as per assignment to ensure timely implementation of new regulations and reflect on business strategy.
- Ensure adherence to Global and local processes & Process improvements: Compliance with Global processes and proactively identify areas of improvement with regards to local compliance.
- Perform other tasks relating to Regulatory activities as assigned.

Minimum Requirements

- University graduate, preferably with a degree in Pharmacy or Medicine
- Fluent in English and Vietnamese, enabling effective local and global collaboration
- 5+ years of experience in Drug Regulatory Affairs or Drug Registration Management
- Strong critical and strategic thinking, with proven communication, influencing, and negotiation capabilities
- Demonstrated independent and innovative mindset, solid understanding of product relevant bioscience, and ability to build trust based relationships with key regulatory authorities

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
Vietnam

站点
Vietnam

Company / Legal Entity
VN04 (FCRS = VN004) Novartis Vietnam Company Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6a4237ce80ae4165835150", 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: "1_dgfvmafo"}}); // 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_data_layer.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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