

## Regulatory Affairs Manager

Job ID  
REQ-10077683

5月 12, 2026

Vietnam

### 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 \(PDF 30 MB\)](#)

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

```
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"1Qm7rm1pm", 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"]) {
```

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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: "1_dgfvmafo"}); } catch (e) { console.error(e.message) }
```

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