

## Regulatory Affairs Associate

Job ID  
REQ-10078046

6月 24, 2026

India

### 摘要

-Provides effective operational and regulatory support to Novartis as well as to regional/global organizations for assigned regulatory submission and maintenance activities, including preparation and submission of regulatory dossiers, maintenance of regulatory databases and archives and artwork-related activities.

### About the Role

Major accountabilities:

- Coordinates and prepares high quality submissions of regulatory dossiers for assigned products -Achieve the CTA/NDA submission on the targeted date; -Achieve the approval of CTA, NDA and other related supplementary application on the targeted date; -Ensure license renewal Submission and approval on time; -Ensure CMC/BPI/PSUR/RMP in line with NMPA regulation and Novartis internal policies; -Ensure registration master file update -Assist to

coordinate f2f meeting with CFDA/CDE for new project discussion -Communicate the questions referred by HAS timely and smoothly; -Timely update and communicate the registration status to the line manager -Timely order and tracking the registration sample, dossier, certificates...; -Start to establish good communication and relationship with key stake holders.

- Get familiar and with company and department SOP and working procedures -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Timely accomplishment of assigned tasks in required quality.
- Compliance with regulations and internal procedures -Relevant databases and archives up -to -date.

Minimum Requirements:

Work Experience:

- Functional Breadth.
- Cross Cultural Experience.
- Operations Management and Execution.
- Project Management.

Skills:

- Clinical Trials.
- Collaboration.
- Databases.
- Detail Oriented.
- Lifesciences.
- Project Planning.
- Regulatory Compliance.

Languages :

- English.

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:
"kalturaplayer6a3ce562e628e681578966", 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 kalturaPlayer =
kPlayer.setup(config); // Add the player to the global array.
window.kalturaPlayerVideos.push(kalturaPlayer); // Load the Player for other media.
kalturaPlayer.loadMedia({entryId: "1_dgfvmafo"}); } catch (e) { console.error(e.message) }

```

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