

Regulatory Affairs Specialist

Job ID
REQ-10086969

9月 03, 2026

South Korea

摘要

The RA specialist sets registration plan and perform product registration in accordance with registration and launch plan, and maintain product license with local regulation and global compliance strategy.

About the Role

Major accountabilities:

- **Major accountabilities**
- Review pipeline and set the registration strategy in collaboration with global RA and related CPO functions with support from senior specialist and manager
- Achieve the best product registration with optimal label by conducting research on submission requirements and approval lead time in accordance with registration plan.
- Support launches (artwork, barcode, Drug ID mark, etc.)

- Perform CTA and get approval to ensure study timeline in collaboration with other CPO functions.
- Support IMP management through confirmation of variant number.
- Maintain product license by managing variations for label, quality (CMC and mfg. site) and administrative changes according to local law/regulation/guidelines, company strategy and global compliance.
- Secure product license by managing Reevaluation/Renewal/Reexamination /HA safety communication
- Ensure post approval activities (website, artwork, etc.)
- Submit RMP by supporting of other function in line with global direction.
- Be accountable for correct and timely update of RA compliance (registration) database (DRAGON)
- Ensure industry compliance with NP4, KRPIA code of conduct
- Support cross functional activities by delivering regulatory input
- Understand basic knowledge on the legal frameworks, internal processes, GxP 's
- Keep abreast of relevant laws /regulations and apply to related CPO activities
- Ensure reporting and follow up of all spontaneous adverse events (AE) and technical complaints for all Novartis products according to respective SOP
- Foster and maintain good relations with internal and external stakeholders.
- Communicate effectively with HA and other BFs
- Understand RA internal working process and handle own task well

- **Essential Requirements**

- Education: 4-year university degree, preferably in Pharmacy, Biochemistry, Chemistry, Life Sciences, or a related field
- Languages: Fluent in both written and spoken English
- Experience: Pharmaceutical industry experience preferred
- Knowledge: Basic understanding of regulatory affairs, drug development process, and applicable pharmaceutical regulations/guidelines preferred

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部门
Development

Business Unit
Development

地点
South Korea

站点
Seoul

Company / Legal Entity
KR01 (FCRS = KR001) Novartis Korea Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Temporary (Fixed Term)

Shift Work
No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6a9bbf4c44813557390941", 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:
```

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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 =
thumbEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbEmbed() 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_datalayer.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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