

Regulatory Affairs Specialist

Job ID
REQ-10086961

9月 03, 2026

South Korea

摘要

-Contributes and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. Supports all registration activities of the Department to ensure compliance with the requisites of the local pharmaceutical regulatory environment.

About the Role

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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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
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:
"kalturaplayer6a9b509e4f502776243662", 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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