

Global Program Regulatory Manager Japan

Job ID
REQ-10076025

4月 16, 2026

Japan

摘要

Prispeva in podpira razvoj predložitve registracije izdelkov, poročil o napredku, dopolnil, sprememb in/ali periodičnih poročil o izkušnjah. Podpira vse registracijske dejavnosti oddelka za zagotavljanje skladnosti z zahtevami lokalnega farmacevtskega regulativnega okolja.

About the Role

Major Accountabilities

- Doseganje najboljše registracije izdelkov s komercialno privlačnim označevanjem v skladu z nacionalno registracijo
- Vzdrževanje in varna licenca za izdelke v smislu CMC/CDS/varnostne posodobitve v skladu z lokalnimi predpisi/zakonom/smernicami, strategijo podjetja in globalno skladnost
- Zagotoviti skladnost z NP4, krpia kodeksom ravnanja, ustreznimi predpisi in zakoni za povezane dejavnosti CPO (dragon update, RMP, pakiranje materialov, promocijska gradiva/dejavnosti,

PMS/poročanje o varnosti drog itd.)

-Spodbujanje in ohranjanje dobrih odnosov z notranjimi in zunanjimi zainteresiranimi stranmi

-Poročanje o tehničnih pritožbah / neželjenih dogodkih / scenarijih posebnih primerov, povezanih z Novartis izdelki v roku 24 ur po prejemu

-Distribucija vzorcev trženja (kjer je primerno)

Key Performance Indicators

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Work Experience

Vođenje operacij in izvrševanje

Vođenje projektov

Funkcionalna širina

Medkulturne izkušnje

Skills

Analitične spretnosti

Načrtovanje projekta

Klinično preskušanje

Sodelovanje

Veščitve o življenju

Detaljno usmerjen

Skladnost s predpisi

Language

Angleščina

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
Japan

站点
Toranomom (NPKK Head Office)

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Redni sodelavec

Shift Work
No

```
var config = { targetId: "kalturaplayer69e20ffa30b48265329264", provider: { widgetId:
"10m7rm1pm", 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"]) {
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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2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
3. <https://novartis.wd3.myworkdayjobs.com/sl-SI/NovartisCareers/job/Toranomon-NPKK-Head-Office/Global-Program-Regulatory-Manager-JapanREQ-10076025-5>
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