

Global Program Regulatory Manager Japan

Job ID
REQ-10076025

4月 16, 2026

Japan

摘要

Draagt bij aan en ondersteunt de ontwikkeling van het indienen van productregistratie, voortgangsrapporten, aanvullingen, wijzigingen en/of periodieke ervaringsrapporten. Ondersteunt alle registratieactiviteiten van het ministerie om ervoor te zorgen dat wordt voldaan aan de vereisten van de lokale farmaceutische regelgeving.

About the Role

Major Accountabilities

- De beste productregistratie verkrijgen met commercieel aantrekkelijke etikettering volgens registratieplan
- Productlicentie onderhouden en beveiligen in termen van CMC/CDS/veiligheidsupdate volgens lokale regelgeving/wet/richtlijnen, bedrijfsstrategie en wereldwijde compliance
- Zorg voor naleving van NP4, KRPIA gedragscode, relevante regelgeving en wetten voor

gerelateerde CPO-activiteiten (DRAGON update, RMP, verpakkingsmateriaal, promotiemateriaal/activiteiten, PMS/drug safety reporting enz.)

-Goede relaties met interne en externe stakeholders onderhouden

-Melding van technische klachten / bijwerkingen / scenario's voor speciale gevallen met betrekking tot Novartis-producten binnen 24 uur na ontvangst

-Distributie van monsters voor het in de handel brengen (indien van toepassing)

Key Performance Indicators

Draagt bij aan en ondersteunt de ontwikkeling van het indienen van productregistratie, voortgangsrapporten, aanvullingen, wijzigingen en/of periodieke ervaringsrapporten. Ondersteunt alle registratieactiviteiten van het ministerie om ervoor te zorgen dat wordt voldaan aan de vereisten van de lokale farmaceutische regelgeving.

Work Experience

Operationeel management en uitvoering

Projectmanagement

Functionele diepgang

Interculturele ervaring

Skills

Analytisch vermogen

Projectplanning

Klinische proeven

Samenwerking

Levenswetenschappen

Detail georiënteerd

Naleving van de regelgeving

Language

Engels

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
Regelmatig

Shift Work
No

```
var config = { targetId: "kalturaplayer69e20ffdc68c5162463125", provider: { widgetId:
"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"]) {
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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