

## **Associate or Manager, PHAD Japan**

Job ID  
REQ-10090367

十月 20, 2026

Japan

### **摘要**

As a CMC development specialist, enhance Japan's CMC development strategy by offering scientific and technical support to global/local CMC development teams and other departments, while keeping up with the latest technological advancements.

### **About the Role**

### **Key Responsibilities**

- **Act as a subject matter expert (SME) on CMC development within the TRD submission team, from initiating clinical trials through NDA filings.**

- **Understand CMC development strategies for assigned projects and provide scientific and technical insights on potential risks, particularly for novel and complex elements.**
- **Develop expertise in new modalities and technologies, including formulations, process development, manufacturing and control strategies, and provide expert consultation.**
- **Provide input on Japanese requirements and expectations, and collaborate with local and global stakeholders to address scientific and technical challenges.**
- **Review and prepare documents, protocols and reports required for Japan filings and launches, including J-NDA Module 3 and J-QOS.**
- **Act as a CMC expert supporting other functions, including knowledge sharing, data generation for marketed products, and collaboration with clinical and commercial stakeholders.**
- **Maintain global and local development-related SOPs and manuals, and perform QC activities for investigational medicinal product (IMP) release in Japan.**
- **Ensure compliance with company requirements and, for manager-level positions, mentor associates and lead activities within PHAD Japan.**

## **Background**

**Education: University or graduate (master's) degree (or higher) in pharmacy, science, engineering, or other technical fields.**

## **Essential Requirements**

- **University or graduate (master ' s) degree or higher in pharmacy, science, engineering or another technical field.**
- **Expertise in at least one CMC area, such as drug substance, drug product, formulation development, process development, setting control strategy or analytical science.**

- **Basic knowledge of Japanese pharmaceutical regulations.**
- **Native-level proficiency in Japanese.**
- **Proficiency in reading and writing in English.**

## **Desirable Requirements**

- **Preferably 5+ years of experience in the pharmaceutical industry.**
- **Intermediate business-level speaking and listening skills in English.**

***\* You do not need to be familiar with all the modalities or technical area mentioned in the Major Accountabilities section. If you have specialized skills in any CMC area and a strong motivation to learn about other technical field, we encourage you to apply.***

**Language skill: Native-level proficiency in Japanese is required, proficiency in reading and writing in English is necessary, and intermediate business-level speaking and listening skills in English are preferred.**

***\* If the candidate possesses exceptional CMC skills, the English language requirements mentioned above can be flexible and open to discussion.***

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any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to [diversityandincl.china@novartis.com](mailto:diversityandincl.china@novartis.com) and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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部门  
Development

Business Unit  
Development

地点

Japan

站点  
本社

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

Functional Area  
Research & Development

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6ad8fabade595933243828", 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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