

Associate or Manager, PHAD Japan

Job ID
REQ-10070486

2月 03, 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

Major Accountabilities

1. Act as a subject matter expert (SME) on CMC development within the TRD submission team to initiating clinical trials through NDA filings. For example:

- Understand the CMC development strategy for assigned projects and provide insights on potential risks to be addressed and/or support the team ' s understanding, especially regarding

novel and complex scientific/technical elements.

- Research and acquire proficiency in topics related to modalities (small molecules including nucleic acids and radioligands, biologics, cell & gene, etc.) and technologies (formulations, process development, manufacturing and control strategy, etc.), and offer expert consultation,
- Input Japanese requirements/expectations in analytical field, seek solutions to challenges through scientific and technical discussions with local and global stakeholders, and review/prepare documents, protocols/reports required for Japan (e.g., specifications & test methods, analytical method validations, stability studies, compatibility studies, and technical experiments required for Japan filings and/or launches),
- Review J-NDA documents such as Module 3 and J-QOS.

2. Act as a CMC expert in supporting other line functions beyond the TRD subteam. For example:

- Learn scientific and technical knowledge for new analytical/manufacturing technologies, new modalities, and new regulations, and share what you learn with TRD members to improve TRD organizational knowledge and capabilities.
- Contribute to data generation (e.g., stability in special conditions, compatibility studies) of marketed products with global stakeholders to support market expectations.
- Provide technical information requested by commercial-related divisions.
- Collaborate with clinical stakeholders to accelerate clinical development in Japan from a CMC point of view.
- Support other requests from functions beyond TRD.

3. Maintain SOPs and development manuals. For example:

- Review and input Japan needs into global development-related SOPs and development manuals.
- Prepare and maintain Japan local SOPs and development manuals.

4. Act as QC function for investigational medicinal product (IMPs) release in Japan. For example:

- Conduct release procedures and retain sample management according to SOPs and other related regulations.

5. Ensure compliance with company requirements. For example:

- Ensure adequate reporting of adverse events, technical complaints, and compliance issues in accordance with company procedures.
- Ensure 100% timely delivery of all training requirements.

6. Serve as a manager. For example:

- Mentor/train associates to become competent players in PHAD Japan.
- Lead various activities in PHAD Japan.

Essential Requirements:

Education:

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

Experience/Professional requirement:

- At least one CMC expertise such as drug substance, drug product, formulation development, process development, setting control strategy, analytical science, etc.
- Basic knowledge of Japanese Pharmaceutical regulations.
- Preferably 5+ years' experience in the pharmaceutical industry.

* 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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<EN>

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<JP>

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互いに協力し、支え合い、刺激し合うことで、患者さんの人生を変えるようなブレークスルーを生み出すことができます。さあ、一緒により明るい未来を創りませんか? <https://www.novartis.com/about/strategy/people-and-culture>

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部門

Development

Business Unit

Development

地点

Japan

站点

Toranomon (NPKK Head Office)

Company / Legal Entity

JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||  
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =  
document.getElementById("kulturaplayer6985e08a2c1e6631961803"); var mediaContainer =  
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";  
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =  
parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles  
of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var  
finalWidth = parseFloat(parentStyles.width); if (finalWidth < originalWidthValue) {  
var config = { targetId:  
"kulturaplayer6985e08a2c1e6631961803", provider: { widgetId: "10m7rm1pm", partnerId:  
"2076321", uiConfd: "55802022" }, playback: { autoplay: false, autopause: false,  
allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: {  
disable: true }, "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 } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false } },  
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',  
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:  
KalturaPlayer.ui.components.Remove } ] }; config.plugins.preventSeek = { preventSeekForward:  
false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = {  
position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-  
js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true };  
config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true };  
config.ui.uiComponents = []; 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"}); setTimeout(() => {  
setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) {  
players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => {  
players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause ===  
'function') { otherPlayer.pause(); } }); });}); } } catch (e) { console.error(e.message) }
```



VIDEO

利便性と合理的配慮

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