

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イ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>

ノバルティス・タレントネットワーク: 今のノバルティスの募集職種がご希望に合わない場合でも、ぜひタレントコミュニティにご登録ください。あなたに合ったキャリアの機会が見つかり次第、いち早くご案内いたします。 <https://talentnetwork.novartis.com/network>

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ノバルティスの福利厚生と報奨について必要な情報は、ノバルティスライフハンドブックに記載されています。 <https://www.novartis.com/careers/benefits-rewards>

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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

```
var config = { targetId: "kalturaplayer69fb39c1d9d0f375267900", 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) }
```

利便性と合理的配慮

ノバルティスは障害を持つ個人と協力し、合理的配慮を提供することをお約束します。健康状態や障害を理由に採用プロセスのいかなる部分においても、あるいは職務の必須事項を果たすために合理的配慮が必要な場合は midcareer-r.japan@novartis.com 宛てに電子メールをお送りください。その際ご依頼内容、ご連絡先、求人票の番号を明してください。

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