

Associate or Manager, PHAD Japan

Job ID
REQ-10070486
фев 03, 2026
Япония

Сводка

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

- 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.
- 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.
- 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.
- 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.
- 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.
- 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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Business Unit
Development
Место
Япония
Сайт
Toranomom (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

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