NOVARTIS

# Associate or Manager, PHAD Japan

Job ID
REQ-10070486
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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

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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<JP>

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Job Type
Full time

Employment Type
Regular
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