NOVARTIS

Associate or Manager, PHAD Japan

Job ID
REQ-10070486
Feb 03, 2026
LOC_JP

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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Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Accessibility and accommodation: Novartis is committed to working with and providing reasonable accommodation to

individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to midcareer- r.japan@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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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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https://talentnetwork.novartis.com/network

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Role Requirements

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