NOVARTIS

Associate or Manager, PHAD Japan

Job ID
REQ-10027187
Oct 23, 2024
Japan

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. (For manager role only) Serve as a manager. For example:

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

Key Performance Indicators

1. Delivered high-quality scientific and technical input and support to meet TRD organizational expectations.
2. Successfully contributed to the delivery of CMC source documents that cover JP requirements and/or agreed mitigation of potential risks in NDA reviews.
3. Contributed to standardization and provided deliverables for global stakeholders to understand JP perspectives.
4. Effectively shared expertise and technological information with the TRD submission team and other functions.
5. Conducted IMP release procedures in a timely manner and contributed to GMP procedure improvement.
6. (For manager role only) Fostered a high-level learning culture, coached associates to grow, and improved/solved organizational challenges.

Background

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.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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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 diversityandincl.china@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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Why consider Novartis?

817million. That's how many lives our products touch. And while we're proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people's lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you're given opportunities to explore the power of digital and data. Where you're empowered to risk failure by taking smart risks, and where you're surrounded by people who share your determination to tackle the world's toughest medical challenges.

We are Novartis. Join us and help us reimagine medicine.

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Japan

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.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.

midcareer-r.japan@novartis.com

Role Requirements

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Division
Development
Business Unit
Innovative Medicines
Location
Japan
Site
Head Office (Japan) (Pharmaceuticals)
Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID
REQ-10027187

Associate or Manager, PHAD Japan

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