NOVARTIS

Associate or Manager, PHAD Japan

Job ID
REQ-10090367
Oct 26, 2026
LOC_JP

About the Role

Key Responsibilities

- **Act as a subject matter expert (SME) on CMC development within the TRD submission team, from initiating clinical trials through NDA filings.**
- **Understand CMC development strategies for assigned projects and provide scientific and technical insights on potential risks, particularly for novel and complex elements.**
- **Develop expertise in new modalities and technologies, including formulations, process development, manufacturing and control strategies, and provide expert consultation.**
- **Provide input on Japanese requirements and expectations, and collaborate with local and global stakeholders to address scientific and technical challenges.**
- **Review and prepare documents, protocols and reports required for Japan filings and launches, including J-NDA Module 3 and J-QOS.**
- **Act as a CMC expert supporting other functions, including knowledge sharing, data generation for marketed products, and collaboration with clinical and commercial stakeholders.**
- **Maintain global and local development-related SOPs and manuals, and perform QC activities for investigational medicinal product (IMP) release in Japan.**
- **Ensure compliance with company requirements and, for manager-level positions, mentor associates and lead activities within PHAD Japan.**

Background

Education: University or graduate (master's) degree (or higher) in pharmacy, science, engineering, or other technical fields.

Essential Requirements

- **University or graduate (master's) degree or higher in pharmacy, science, engineering or another technical field.**
- **Expertise in at least one CMC area, such as drug substance, drug product, formulation development, process development, setting control strategy or analytical science.**
- **Basic knowledge of Japanese pharmaceutical regulations.**
- **Native-level proficiency in Japanese.**
- **Proficiency in reading and writing in English.**

Desirable Requirements

- **Preferably 5+ years of experience in the pharmaceutical industry.**
- **Intermediate business-level speaking and listening skills in English.**

*** 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.**

Benefits and Rewards

Read our handbook to learn about all the ways we'll help you thrive personally and professionally:

https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

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 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.

Additional Information

Be aware of fake job advertisements and job offers. Novartis does not make job offers without interviews and never asks candidates for money. All our current job openings are displayed here. If you have encountered a job posting or been approached with a job offer that you suspect may be fraudulent, we strongly recommend you do not respond, send money, or provide personal information.

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Role Requirements

Division
DIV_GD
Business Unit
Development
Location
LOC_JP
Site
本社
Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.
Functional Area
FCT_RD
Job Type
Full time
Employment Type
Regular
Shift Work
No

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