Senior Manager, RA CMC

Job ID
REQ-10065991

11月 04, 2025

Japan

摘要

Responsible for submission document preparation concerning CMC parts of NDA, PCA (Partial Change Application) and NMC (Notification of Minor Change) according to the agreed timelines to get the approval in Japan.

With regard to Marketed Products, responsible for regulatory evaluation for change requests generated at manufacture sites etc. based on Japanese guidelines and notifications.

About the Role

Job Description

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Key Responsibilities:

1. Manage overall RA CMC Japan processes and resources and represent RA CMC Japan to ensure the major accountabilities for RA CMC Japan listed in 2 and later below (As a line manager)

2. Contribute to TRD-Japan sub team for project development and submission

- Make the input into development strategy from regulatory CMC perspective

- Provide and/or manage CMC documents during project development

- Prepare submission documents (CTD document and Application Form) in line with the agreed timeline

- Prepare answer for PMDA inquiry working closely with relevant line functions

3. Support or Lead Change Control Management for marketed product - Provide accurate regulatory evaluation for change request generated at manufacture site and elaborate submission strategy and timeline with relevant line functions

- Prepare Application Form and necessary submission document in collaboration with global RA CMC and submit

- Manage communication with Japan Health authority and prepare quality answer for PMDA inquiry after PCA submission to get approval timely

4. Contribute to development and post market maintenance of new modalities/technologies (e.g. CG&T products, nucleic acid drugs, radioligand therapy, medical devices, etc.)

- Provide robust regulatory strategies and CMC documents at development

- Contribute to stable supply by making appropriate change controls

- Lead regulatory intelligence and strengthen CMC regulatory expertise

(As a line manager)

5. Maintain the contents in various databases to share Japan status on marketed products precisely and transparently with all the stakeholders

6. Maintain latest CMC regulatory intelligence in Japan and inform global RA CMC and other relating members timely and appropriately. Ensure regulatory compliance for all RA CMC deliverables

7. Support or Lead divestment and pruning activities and third party customers for marketed products in line with business strategy

8. Ensure that a timely and effective communication and escalation process is communicated to and followed by all personnel in their respective area. (As a line manager)

9. Advocate continuous improvement of quality. (As a line manager)

10. Ensure all activities of associates comply with company standards and local regulations. (As a line manager)

11. Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures.

12. 100% timely delivery of all training requirements including compliance.

Essential Requirements:

Education:

· Degree in pharmacy, science, agriculture, technical and pharmaceutical engineering discipline required and more advanced degree preferable.

Experience/Professional requirement:

· 6-8 years or more experience in pharmaceutical industry.

· Possess extensive and excellent technical, scientific and/or regulatory CMC knowledge in drug development and/or maintenance.

· Experience in strategic and excellent interfacing with PMDA and MHLW regarding CMC area.

· Experience in working in a global environment.

· Address RA CMC related issues by leading/working across relevant line functions and implement action plans.

· Train and mentor/coach RA CMC members concerning regulatory requirements and intelligence.

· Demonstrated ability for innovative and big picture thinking.

・ Have the ability to participate in industry group activities as a representative of the Novartis Japan, and ex-press opinions positively and lead the industry's other members.

・ Discuss local regulatory strategies at global level in English.

English Skill:

・ Fluent English as business language

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病気と向き合う人々やそのご家族を支えるには、革新的な科学だけでは不十分です。それには、あなたのような情熱と知性を持った仲間が必要です。

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

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部門

Development

Business Unit
Development

地点
Japan

站点
Toranomon (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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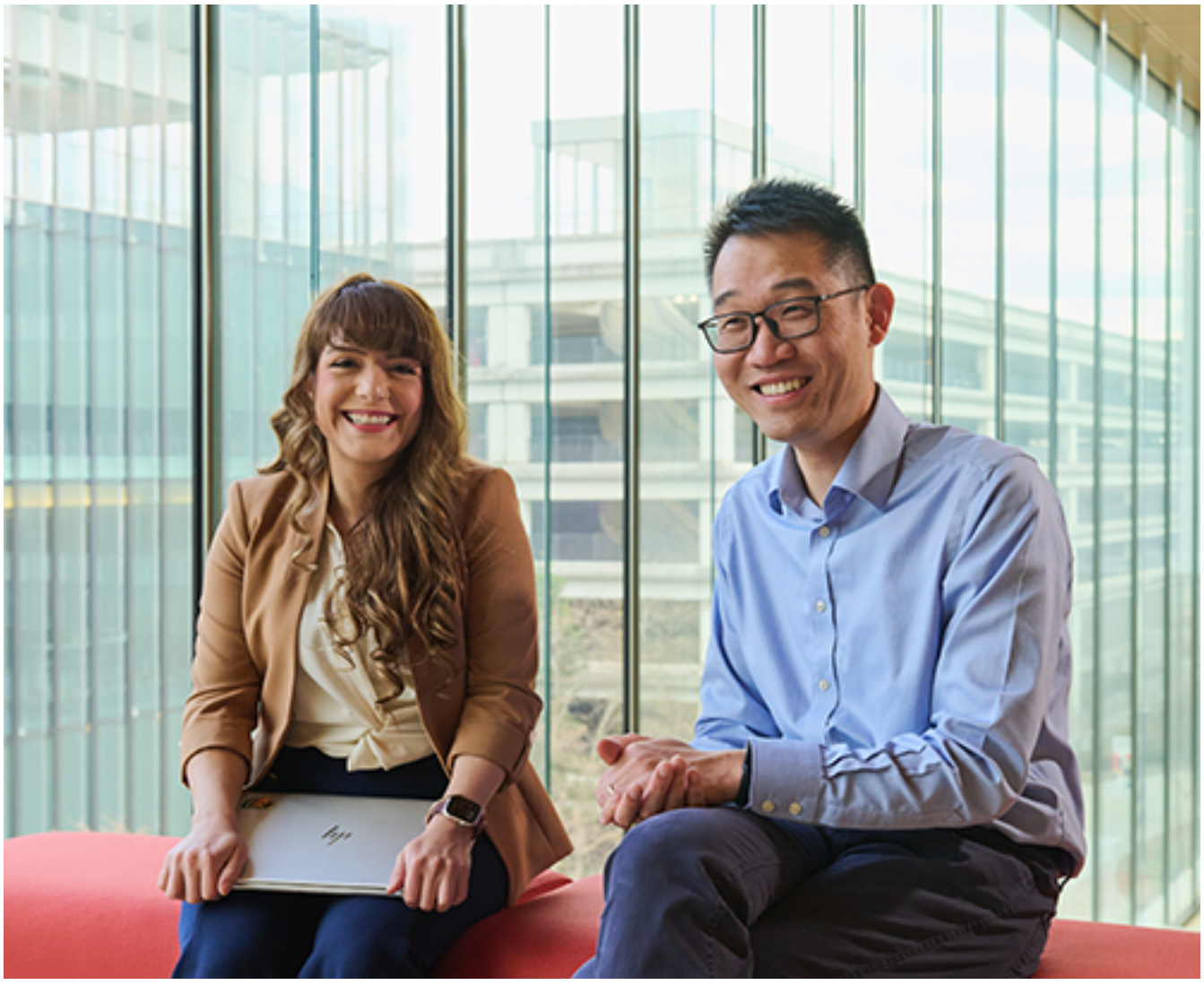

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