Manager, RA CMC Manager Japan

Job ID
REQ-10031483

3月 13, 2025

Japan

摘要

化学、製造、および制御(CMC)に関する規制活動を担当。保健当局への提出のためのREG CMC文書の準備と公開などの活動。さらに、新製品をサポートしたり、発売後に発売を開始したりするために、REG CMCに関するHAとやり取りします。

About the Role

Major Accountabilities

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

Lead and implement 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

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

Maintain the contents in various databases to share Japan status on marketed products precisely and transparently with all the stakeholders 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 Support divestment and pruning activities and third party customers for marketed

products in line with business strategy

Ensure adequate reporting of adverse events/ technical complaint/ compliance issue in accordance with company procedures. 100% timely delivery of all training requirements including compliance.

Background

Education:

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

Experience/Professional requirement:

3 years or more experience in pharmaceutical industry. Possess extensive technical, scientific and/or regulatory CMC knowledge in drug development and/or maintenance.

Experience in interfacing with PMDA and MHLW regarding CMC

area.

Experience in working in a global environment.

Address RA CMC related issues across relevant line functions and

implement action plans.

Train RA CMC members concerning regulatory requirements and

intelligence.

English Skill:

Fluent English as business language

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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/novartiscom/files/novartis-life-handbook.pdf

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Benefits and Rewards: Read our handbook to learn about all the ways we 'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Universal Hierarchy Node

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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利便性と合理的配慮

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