RA CMC Manager Japan

Job ID
REQ-10059648

8月 19, 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

Your responsibilities include, but not limited to:

1. Contribute to Japan sub team for project development and submission

- Lead or manage 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

2. 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

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

4. 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

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

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

7. 100% timely delivery of all training requirements including compliance.

RA
CMCは、 CMCに係るサイエンスや薬事の知識に基づき、 NPKK
のすべての開発品および市販品を、開発段階から製品ライフサイクルの終了までカバー
しています。また、 CMC
薬事に関して、規制当局と直接交渉を行います。新しい医薬品や治療を患者さんのもとへできるだ
け早く届けるとともに、それらの製品を安定的
に提供し続けるNPKKのミッションにCMCの立場からdirectに貢献する役割を担っています。

応募資格

Education, Work experience and Competency:

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 regulatory affairs CMC or a related pharmaceutical field.

- 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.

- It would be more preferable if there is work experience in development/submission or post-approval change control of radiopharmaceuticals

English Skill:

- Fluent English as business language (including English communication skill)

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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

Apply to Job

利便性と合理的配慮

ノバルティス は 障害 を 持 つ 個人 と 協力 し、合理的配慮 を 提供 すること をお 約束 します。健康状態 や 障害 を 理由 に 採用 プロセス のいかなる 部分 においても、あるいは 職務 の 必須事項 を 果 たすた めに 合理的配慮 が 必要 な 場合 は midcareer-r.japan@novartis.com 宛 てに 電子 メール をお 送 りください。その 際 ご 依頼内容、ご 連絡先、求人票 の 番号 を 明 してください。

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