

Manager, RA CMC Manager Japan

Job ID
REQ-10031483

12月 03, 2024

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

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>

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>

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.

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

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

Innovative Medicines

地点

Japan

站点

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](#)

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。



Job ID
REQ-10031483

Manager, RA CMC Manager Japan

[Apply to Job](#)

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10031483-manager-ra-cmc-manager-japan-ja-jp>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
3. <mailto:diversityandincl.china@novartis.com>
4. <https://talentnetwork.novartis.com/network>
5. <https://www.novartis.com/about/strategy/people-and-culture>
6. <https://talentnetwork.novartis.com/network>
7. <https://www.novartis.com/careers/benefits-rewards>
8. <https://novartis.wd3.myworkdayjobs.com/ja-JP/NovartisCareers/job/Head-Office-Japan-Pharmaceuticals/Manager--RA-CMC-Manager-JapanREQ-10031483-2>
9. <mailto:midcareer-r.japan@novartis.com>
10. <https://novartis.wd3.myworkdayjobs.com/ja-JP/NovartisCareers/job/Head-Office-Japan-Pharmaceuticals/Manager--RA-CMC-Manager-JapanREQ-10031483-2>