

Manager, RA CMC Manager Japan

Job ID
REQ-10031483
Dic 03, 2024
Giappone

Sommario

(CMC)

REG CMC

REG CMC HA

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>

Divisione

Development

Business Unit

Innovative Medicines

Posizione

Giappone

Sito

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](#)

[midcareer-](#)

r.japan@novartis.com

Job ID

REQ-10031483

Manager, RA CMC Manager Japan

Source URL: <https://www.adacap.com/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/novartis_com/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/Novartis_Careers/job/Head-Office-Japan-Pharmaceuticals/Manager--RA-CMC-Manager-Japan_REQ-10031483-2
9. <mailto:midcareer-r.japan@novartis.com>
10. https://novartis.wd3.myworkdayjobs.com/ja-JP/Novartis_Careers/job/Head-Office-Japan-Pharmaceuticals/Manager--RA-CMC-Manager-Japan_REQ-10031483-2