NOVARTIS

Manager, Global Program Regulatory Manager (GPRM) Japan

Job ID
REQ-10027926
Oct 31, 2024
Japan

Summary

Contribute to the overall activities in drug development* toward obtaining the marketing authorization and maintenance activities of post marketing products in assigned TA area.
* Drug development including development of drug, medical device, companion diagnostics and tissue-engineered medical products

About the Role

Major accountabilities:

- Assist developing innovative and high quality regulatory strategies to facilitate regulatory processes in development and ensure registration with optimized labels that contribute to health and welfare of the Japanese nation.
- Contribute to the regulatory activities in day-to-day operations for assigned TA area.
- Lead cross functional communication for preparing and finalizing Japanese labeling for new drugs.
- Lead regulatory related actions to maintain post marketing products in Japan.
- Establish strong relationship with the Japanese HA and obtaining high credibility in responsible projects.
- Ensure adherence to regulations, guidelines and global/internal procedures as required.
- Represent RA within specific internal discussions across line functions and external industry meetings.
- Mentor RA associates on drug development.
- Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures.
- 100% timely delivery of all training requirements including compliance.

Key performance indicators:

- Achieve planned submission and approval in time in responsible projects.
- Obtain preferable outcomes of PMDA consultation in development phase projects for which the GPRM-J is responsible.
- No critical problem for maintaining post marketing product in responsible projects.
- Fulfil regulatory responsibilities in Japan to the GPT/GBT and RA subteam, and achieve registration with the best possible labeling.

Minimum Requirements:
Work Experience:

- Train and mentor RA members concerning drug development.

- Understand varied knowledge of Japan regulation.
- Possess extensive knowledge of MHLW/PMDA management, structures and organizations, and maintain trustful working relationship with MHLW/PMDA.
- Contribute to discussions on licensing conditions and integrate legal considerations into regulatory strategy.
- Possess extensive scientific knowledge of assigned TA/disease area, and facilitate scientific interactions between experts relevant for drug development/maintenance.
- Address scientific issues across line functions and implement action plans.
- Define internal procedures for complying with effective regulatory requirements and enhancing quality and efficiency of the processes.
- Effectively negotiate with cross functional teams and lead an agreement in the optimal solution, and manage internal/external negotiation on development strategies and business critical issues.
- Excellent in effectively making presentation to clarify discussion items and raise key points to focus on in English.
- Contribute drug development planning by integrating expertise in the regulatory, legal and business environments.
- Possess extensive knowledge of global regulatory environment, and take appropriate actions to resolve issues identified in the projects that may negatively affect development strategy and progress.

Education :

- Degree in pharmacy, medicines, science, agriculture and/or pharmaceutical engineering discipline required. Advanced degree (Master Degree, PhD, etc.) preferred.
- Pharmacist license preferred.

Languages :

- Fluent English as business language.

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Business Unit
Innovative Medicines
Location
Japan
Site
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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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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