Manager, GPRM Japan（薬制薬事）

Job ID
REQ-10054039
Jul 01, 2025
Japan

Summary

Contribute to the development and implementation of regulatory strategy for postapproval regulatory objectives* for stable supply of marketed products including
maintenance of regulatory licenses.
The GPRM of RA LCM-J works in close collaboration with Development, NTO, CPO QA and BFU as well as Global RA LCM member.
* Regulatory objectives for post approval commitments, re-examination/re-evaluation, divestment, stock-out/recall, Japanese Pharmacopoeia listing etc.

About the Role

＜主な職務内容＞

薬制薬事担当として、主に以下の業務に従事頂きます。

- 外国製造業者認定の維持・管理業務
- 医薬品製造販売業許可、再生医療等製品製造販売業許可の維持・管理業務
- 市販後の製品維持に向けた品質保証、CMC、生産部門等との連携及びプロジェクトマネジメント業務
- 承継、承認整理における薬事業務

Regulatory Strategy
1. Assist high quality and aligned regulatory strategies to complete post-approval regulatory objectives
2. Lead the team to keep stable product supply and/or avoid risks on the Japanese patients
3. Contribute operational and strategic regulatory input into related functions for stable supply of marketed products
4. Align on regulatory strategy in order to fulfill business objectives in collaboration with global

HA interactions, Submissions and Approvals
1. Lead regulatory related actions to maintain post-approval regulatory activities in Japan.
2. Establish high quality and professional interactions with the Japanese HA and obtaining high credibility in responsible projects.

License maintenance and accreditation

1. Ensure appropriate MA license maintenance with leading regular inspections
2. Ensure appropriate site accreditations and timely implementation of information changes.

Managerial

1. Advise GPRMs-J to provide strategic regulatory input into post-approval regulatory objectives
2. Mentor GPRMs-J in post-approval regulatory activities.
3. Consider synergy where appropriate across the related functions for post-approval regulatory objectives at not only Japan but also global
4. Ensure timely, clear communications on project/ issues/ risks/ regulatory status with teams, RA-J line managers and key stakeholders across the division internally. Global communication with RA LCM and with HA also is appropriately conducted.
5. Contribute to drive efficiently while maintaining quality

Regional excellence and Compliance

1. Ensure compliance with global/Japan regulatory requirements and adherence to internal policies and processes and coordinate compliance activities at a country level.
2. Oversee and provide support as needed for non-project related country excellence activities

Education:

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

Languages:

Proven communication skill in Japanese. Fluency in English as a business language.

Experience/Professional Requirement:

1. Train and mentor RA members concerning drug development
2. Understand varied knowledge of Japan regulation
3. Possess extensive knowledge of MHLW/PMDA management, structures and organizations, and maintain trustful working relationship with MHLW/PMDA.
4. Contribute to discussions on licensing conditions and integrate legal considerations into regulatory strategy.
5. Possess extensive knowledge of post-approval regulatory, and facilitate reasonable interactions between experts relevant for drug development/maintenance.
6. Address issues across line functions and implement action plans.
7. Define internal procedures for complying with effective regulatory requirements and enhancing quality and efficiency of the processes.
8. Effectively negotiate with cross functional teams and lead an agreement in the optimal solution, and manage internal/external negotiation on development and business critical issues.
9. Excellent in effectively making presentation to clarify discussion items and raise key points to focus on in English.
10. Possess extensive knowledge of regulatory environment, and take appropriate actions to resolve issues identified in the activities.

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Business Unit
Universal Hierarchy Node
Location
Japan
Site
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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