Sourcing only, Associate/Manager Regulatory Affairs / CMC " >

Job ID
306958BR
Nov 23, 2021
Japan

Job Description

5! The number of projects you will be leading to develop our growing pipeline of Gene Therapy products. We are looking for an experienced professional in the area of drug product development for Gene Therapy-based drug products, with special focus on viral vectors.

1. 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 with obtaining support from GPRM-J/Head of RAU-J,.
2. Contribute to the regulatory activities in day-to-day operations for assigned TA area with obtaining support from GPRM-J/Head of RAU-J.
3. Lead cross functional communication for preparing and finalizing Japanese labeling for new drugs with obtaining support from GPRM-J/Head of RAU-J..
4. Take regulatory related actions to maintain post marketing products in Japan with obtaining support from GPRM-J/Head of RAU-J..
5. Establish goodrelationship with the Japanese HA in responsible projects with obtaining support from GPRM-J/Head of RAU-J.
6. Contribute to the adherence to regulations, guidelines and global/internal procedures .
7. Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures
8. 100% timely delivery of all training requirements including compliance

Job Sourcing Statement

You are applying to be part of the Novartis Talent Pool. We are not currently recruiting for this role but we are building a pipeline for future opportunities. If you would like to be considered for a similar position in future, then please submit your CV.

Minimum Requirements

Education:
• Degree in pharmacy, medicines, science, agriculture and/or pharmaceutical engineering discipline required. Advanced degree (Master Degree, PhD, etc.) prefered.
• Pharmacist license preferred.
Experience/Professional requirement:
1. Demonstrate good presentation skills in delivering clear messages to audience and modifying language and style to meet the needs from audience.
2. Understand the drug development/maintenance processes, milestones in the assigned disease area and

Novartis procedures for decision board review and approval.
3. Understand basic knowledge of Japan regulation
4. Possess basic knowledge of global regulatory environment, and contribute to elaborating the project specific development/regulatory strategy and plan.
5. Report and summarize discussions in which RA plays an important role.
6. Good in writing and reading English (e.g. exchange of scientific and technical information by e-mail and generation of scientific and technical documentation).
7. Proactively communicate issues and potential solutions.
8. Provide updates on current situation, and ensure that the same information is disseminated throughout the organization as needed.
9. Network with others and share information.
10. Demonstrate cultural awareness and work in cross cultural environment.

English Skill: Fluent English as business language.
Division
Global Drug Development
Business Unit
REG AFFAIRS GDD
Location
Japan
Site
Tokyo
Company / Legal Entity
Novartis Pharma K.K.
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No
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