

Manager, TRD Project management

Job ID
REQ-10025830
Oct 16, 2024
Japan

Summary

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~ (ICH) (GCP) (GMP) ~

About the Role

Job Purpose

Contribute to development, submission, approval and launch of Novartis products in Japan from technical development viewpoints.

Represent TRD in JPT and represent TRD-J in global TRD sub team.

Interact with TM-J for evaluation of early phase projects and for ESS.

Interact with PharmOps-J and/or Marketing-J for appropriate technical development and successful launch in Japan.

Major Accountabilities

Represent TRD-J in the TRD sub team for assigned projects Represent TRD in the JPT for assigned projects Assure progress (science, time, cost) on assigned project in TRD-J, share the information with global TRD, and input Japan specifics to TDP and PDC for assigned projects Lead TRD-J sub team for assigned projects Plan and monitor TRD-J contribution to project (discuss & coordinate activities within Japanese line functions). Elaborate/ monitor TRD-J budget Interact with TM-Japan for projects in assigned therapeutic area Evaluate early phase projects to propose Japanese input for global sPoC proposal Support preparation of ESS, e.g. drug supply, compatibility, etc. Interact with PharmOps-J and Marketing-J for appropriate technical development and successful launch in Japan for assigned projects Evaluate projects at any global stage before JPT is formed (GPT exists but JPT is not formed) for projects in assigned therapeutic area Support Due Diligence in Japan on demand base Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures 100% timely delivery of all training requirements including compliance

Education:

- Technical or scientific university degree
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Experience/Professional requirement:

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- Experience of CMC roles in the pharmaceutical industry
- Solid knowledge of regulatory environment
- Experience of working in a global environment
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English Skill:

- Fluent: oral and written

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Japan

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Division

Development

Business Unit

Innovative Medicines

Location

Japan

Site

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

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