

Head, Clinical Development Division 3

Job ID
REQ-10060952

9月 08, 2025

Japan

摘要

The Head of Clinical Development Division (CDD Head) is responsible to oversee study level activities related to the clinical development and Post Marketing under the GCP/GPSP and Re-examination system and promote close collaboration between CDD-J and JPCH.

The CDD Head leads overall strategy for the CDD, guiding CDD-Js and cultivates CDD-J's talent & career development and reinforce company/organizational missions.

About the Role

1) Maintain high quality of documents related to clinical development and Postmarketing activities in compliance with related regulations, SOPs and other related procedures 2) Support discussion of study concept, interim/final study report (CSR), the postmarketing data package and PVP strategy proposed by CDD-J and Teams based on latest regulation, internal/external information and CD&A's direction. 3) Oversee to CDD-J's trial level activities of clinical development and CDD-J's supports for program level regulatory documents and safety reporting (e.g., Investigator's Brochures, briefing

books, safety updates, CTD, RE-examination application, the other submission dossiers responses to Health Authorities, Periodic Safety Update Reports, Drug Safety Update Reports and other safety related documents) 4) Gather and input latest clinical trial/PMS/drug development trend/information and enhance innovative approach in the clinical development and post launch area to maximize data utilization and lead the industry. 5) Enhance CDD-J 's skills, maximize their abilities through daily work, role based training, OJT, etc. provide on-boarding, training & mentoring support, and cultivate their talent & career development. 6) Ensure adequate reporting of adverse events/ technical complaints/ compliance issues in accordance with company procedures. 7) Lead or serve on Japan process improvement work streams, act as Subject Matter Expert for SOP or trainings, and/or contribute to cross-functional initiatives 8) 100% timely delivery of all training requirements including compliance 9) Expand our external network to maximize the scientific values gained in the post launch phase.

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部门

Development

Business Unit

Universal Hierarchy Node

地点

Japan

站点

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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