Manager, TRD Project management

Job ID
REQ-10025830

10月 16, 2024

Japan

摘要

これは、機能や部門間で共通するこの役割の主要な職務のいくつかを捉えることを目的とした普遍的な職務記述書です。ポジションの特定の責任のすべてを表すことを意図したものではありません~割り当てられた供給活動に対して運用上のエンドツーエンドの責任があります。さまざまな複雑さのプロジェクトとローカルネットワーク活動を主導および管理し、部門横断的なチームに参加します.臨床試験で使用される医薬品の製造、パッケージ化、製造。ヒト用医薬品の登録に関する技術要件の調和に関する国際会議(ICH)、適正臨床基準(GCP)、および適正製造基準(GMP)のガイドラインに準拠した臨床試験用材料の流通、倉庫保管、輸送、包装、無作為化、盲検化、およびラベリングを担当します割り当てられた供給活動に対してエンドツーエンドの運用責任を負います。要求の厳しいプロジェクトやネットワーク活動を主導および管理し、部門横断的なチームに参加します。

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 therapic 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 therapic 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

Experience/Professional requirement:

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

English Skill:

- Fluent: oral and written

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients ' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf

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Why consider Novartis?

817million. That ' s how many lives our products touch. And while we ' re proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people ' s lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you ' re given opportunities to explore the power of digital and data. Where you ' re empowered to risk failure by taking smart risks, and where you ' re surrounded by people who share your determination to tackle the world ' s toughest medical challenges.

We are Novartis. Join us and help us reimagine medicine.

ノバルティスの製品は約8億人以上の患者さんに世界中で届けられています。

約10万の社員が世界中のノバルティスで働いており、その国籍は約 147カ国に及びます。

ノバルティスファーマ株式会社は、スイス・バーゼル市に本拠を置く医薬品のグローバルリーディングカンパニー、ノバルティスの日本法人です。ノバルティスは、より充実したすこやかな毎日のために、これからの医薬品と医療の未来を描いています。詳細はホームページをご覧ください。 https://www.novartis.co.jp

Japan

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宛てに電子メールをお送りください。その際ご依頼内容、ご連絡先、求人票の番号を明記してください。

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部門
Development

Business Unit
Innovative Medicines

地点
Japan

站点
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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利便性と合理的配慮

ノバルティス は 障害 を 持 つ 個人 と 協力 し、合理的配慮 を 提供 することをお 約束 します。健康状態 や 障害 を 理由 に 採用 プロセス のいかなる 部分 においても、あるいは 職務 の 必須事項 を 果 たすた めに 合理的配慮 が 必要 な 場合 は midcareer-r.japan@novartis.com 宛 てに 電子 メール をお 送 りください。その 際 ご 依頼内容、ご 連絡先、求人票 の 番号 を 明 してください。

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