NOVARTIS

Senior Scientist - Preclinical Safety

Job ID
REQ-10082103
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Япония
で利用可能: 日本語

Сводка

Drive regulatory submission excellence and early-stage development strategy by authoring high-quality Japanese New Drug Applications and providing pharmacology or toxicology expertise to clinical programs in Japan.

About the Role

職務内容

- 非臨床安全性担当者としてプロジェクトチームに参画しチームメンバーと協働し開発を推進する。
- Globalメンバーの一員として，国内外の開発に非臨床安全性担当者として貢献する。

主な役割責任

- 早期化合物の安全性評価を行いチームへ適切に評価内容を伝える。
- 承認申請資料を作成し，当局からの照会回答を含む承認申請全般に責任をもつ。
- 治験届に関する資料作成を行い，当局からの照会対応を含む治験届業務全般に責任をもつ。
- 当局に対する相談について非臨床安全性担当者として責任をもつ

必須要件

- ライフサイエンス分野で修士以上，もしくはそれと同等の学位を有する（PhD, DVM等）。
- 非臨床安全性分野での業務経験を有する。GLP環境下での毒性試験経験，または委託試験経験を有する。
- 国内外の非臨床安全性に関するガイドラインを周知しており，活用できる。
- 日本語は母国語相当及び英語は流暢(口頭および書面)

望ましい要件

- 放射線治療薬，遺伝子治療薬，細胞医療等製品，又は核酸医薬品等の最新のモダリティーの毒性評価の経験を有する。
- 生殖発生毒性試験や毒性病理，遺伝毒性など毒性学的専門領域を有する。
- AIを用いた毒性評価経験

Major Accountabilities

· Authoring responsible parts of J-NDAs, response to PMDA and all of the other activities for submission if necessary.

· Assessment of pharmacological and/or toxicological profiles of early projects to contribute to Japan development strategy.

· Roles as JPT/JST members

· Support of TM clinical studies as pharmacologists and/or toxicologists including protocol/ICF review, IB review and interaction with HAs.

· Seeking opportunity of proposals about new development programs/ indications

· Participate/support initiatives, task-forces, and cross-functional activities in Dev./NPKK.

· Quality management responsibility

- Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures

- 100% timely delivery of all training requirements including compliance

Key Performance Indicators

· Appropriate quality and timing of NDA and post NDA activities

· Appropriate quality and timing of pharmacological and/or toxicological profiling/evaluation of early projects

· Appropriate quality and timing of study supports

Background

Education: MSc or PhD in life sciences (Pharmacology, toxicology, Pharmaceutics, other specific sciences), DVM/MD or equivalent professional experience.

· Experience/Professional requirement:

· Taking education or possessing knowledge of basic medicine, such as physiology, pharmacology, toxicology, anatomy/histology, molecular biology, etc.

· For mid-carrier employee, experience in pharmacology, toxicology or relevant field of the pharmaceutical Industry, CRO, academia, etc.

English Skill:

Appropriate skills of English (read/write and oral)

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/novartis_com/files/novartis-life-handbook.pdf

Commitment to Diversity and Inclusion

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Accessibility and Accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Additional Information

Be aware of fake job advertisements and job offers. Novartis does not make job offers without interviews and never asks candidates for money. All our current job openings are displayed here. If you have encountered a job posting or been approached with a job offer that you suspect may be fraudulent, we strongly recommend you do not respond, send money, or provide personal information.

Join our Novartis Network:

Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Biomedical Research
Business Unit
Development
Место
Япония
Сайт
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

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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