Regulatory Affairs Manager

Job ID
REQ-10020963

9月 01, 2024

China

摘要

指导提交产品注册、进度报告、补充、修订和/或定期经验报告的进度。
为团队进行交互沟通提供战略性产品指导，并与监管机构协商证据。
与监管机构人员进行沟通和协商，以加快批准未决注册并回答任何问题。
在整个产品生命周期中担任项目团队的监管联络员。确保快速及时批准新药、生物制品/生物技术和/或医疗器械，并确保上市药品或医疗器械的持续批准状态。
担任市场营销或研究项目团队和政府监管机构的监管代表。
向开发和/或营销团队提供有关制造变更、生产线扩展、技术标签、适当法规和解释的建议。
协调、审查，或编制要提交的报告。

About the Role

Key Responsibilities：

- Provide regulatory inputs in new project development strategy discussion;

- Lead or coordinate both local and global team on registration plan;

- Be accountable on the implementation the decided project registration strategy by projects planning and tracking; Be accountable on achieving the target timeline of submission and approval; Be accountable on the communication with HAs to properly address the concerns on projects; and the coordination on related HA meetings; Be accountable on the communication with Global team on the related regulatory issues on the responsible projects; Be accountable for ensuring regulatory compliance for the responsible brands like CMC, BPI, PSUR, RMP, registration master file and timely update in DRAGON;

- To solve the regulatory issues via communication and negotiation with HAs if necessary; Review/approve of promotional materials and press releases for NP4 Managerial (MCC review);

- Lead or chair the CPT meetings for responsible project and be accountable to provide regulatory support to other functional team;

- Contribute to optimize DRA internal operational procedures whenever is needed. Ensure regulatory activities comply with Novartis internal Code of Conduct and SOPs/WIs during routine work; Monitor regulatory changes and report to department head timely; Support line manager to control project cost according to budget; Coach the junior levels ;

- Acting as deputy in the absence of the department head and lead team daily operation

Commitment to Diversity and Inclusion / EEO:

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

Essential Requirements:

- At least 4 years in RA and/or drug/biologic; Development which include 2-3 years and above of demonstrated accomplishment in RA filed;

- The experience in filing global trial CTA independently;

- The experience in filing and obtaining NDA approval;

- The experience in various types of regulatory submission/approvals;

Desirable Requirements:

- Bachelor or above with Pharmaceutical/Medical background;

- Fluency in English and Chinese (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

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.

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. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

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

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

Benefits and Rewards: Read our handbook to learn about all the ways we 'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Innovative Medicines

地点
China

站点
Beijing (Beijing)

Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
正式

Shift Work
No

Apply to Job

无障碍及便利 设 施

诺华 承 诺 与残障人士共事并 为 他 们 提供合理的便利 设 施。如果您由于健康状况或残障 在招聘 过程的任何 环 节 需要合理便利 设 施 或者 为 了履行 职 位的基本 职 能 请发 送 电 子 邮 件至 diversityandincl.china@novartis.com 告知您的需求和 联 系方式，并在 邮 件中附上您的 职 位申 请编号。

Job ID
REQ-10020963

Regulatory Affairs Manager

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10020963-regulatory-affairs-manager-zh-cn

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf
3. mailto:diversityandincl.china@novartis.com
4. https://talentnetwork.novartis.com/network
5. https://www.novartis.com/about/strategy/people-and-culture
6. https://talentnetwork.novartis.com/network
7. https://www.novartis.com/careers/benefits-rewards

8. https://novartis.wd3.myworkdayjobs.com/zh-CN/NovartisCareers/job/Beijing-Beijing/Regulatory-Affairs-ManagerREQ-10020963-1
9. mailto:diversityandincl.china@novartis.com
10. https://novartis.wd3.myworkdayjobs.com/zh-CN/NovartisCareers/job/Beijing-Beijing/Regulatory-Affairs-ManagerREQ-10020963-1