

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.

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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

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