Regulatory Affairs Manager

Job ID
REQ-10020963
Sep 01, 2024
China

Summary

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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/novartis_com/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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Division
Development
Business Unit
Innovative Medicines
Location
China

Site
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

Shift Work
No
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