(Senior) Regulatory Affairs Manager

Job ID
REQ-10038148

2月 05, 2025

China

摘要

About the role:
In this role, you will be accountable for regulatory strategy development and the implementation of the registration strategy in China.

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).

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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
Regular

Shift Work
No

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