

Regulatory Affairs Manager

Job ID
REQ-10020963
Sep 01, 2024
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).

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>

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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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<https://talentnetwork.novartis.com/network>. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

Role Requirements

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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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List of links present in page

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