

# Regulatory Affairs Manager

Job ID  
REQ-10020963  
Set 01, 2024  
Cina

## Sommario

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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).

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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](mailto: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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