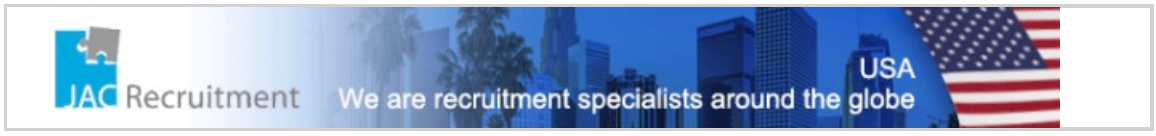
CareerCross by JAC Recruitment



PR/086656 | Regulatory Affairs Manager

募集職種

人材紹介会社
JAC Recruitment USA

求人ID
1537861

業種
医療機器

雇用形態
正社員

勤務地
アメリカ合衆国

給与
経験考慮の上、応相談

更新日
2025年05月15日 10:01

応募必要条件

職務経験
3年以上

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
ビジネス会話レベル

最終学歴
短大卒： 準学士号

現在のビザ
日本での就労許可は必要ありません

募集要項

Regulatory Affairs Manager

A global medical manufacturer is seeking a Regulatory Affairs Manager. This role supports the Director in formulating and implementing regulatory strategies, managing the team, and ensuring compliance in the US, Canada, Latin America, and assigned Asian countries, in line with the goals of GCA companies and divisions (GCA, LATAM, GCOA, GCMA). The position reports to the Director of Regulatory Affairs and Product Engineering.

RESPONSIBILITIES
Regulatory Compliance and Documentation:

- Manage change control and LTF processes, ensuring compliance with FDA, EPA, and LATAM regulations.
- Oversee the preparation and review of dossiers and documents, ensuring timely renewal of facilities and product licenses in the US, Canada, and other countries.
- Monitor regulations by FDA, Health Canada, COFEPRIS, ANVISA, and others, designing strategies for compliance with new and existing regulations.

Team Management and Leadership:

- Create, motivate, lead, and evaluate small to mid-size teams to achieve department and corporate goals.

- Work with the Director in budgeting, regulatory strategy, goal setting, and motivation of team members.
- Coordinate cross-functional teams and consultants, managing the regulatory team and organizing weekly meetings for tracking RA projects and tasks.

Strategic Planning and Implementation:

- Assist the Director in managing and leading strategy formulation and implementation to create greater efficiency and improve regulatory processes.
- Organize regulatory strategies into PowerPoint presentations and reports for the RA Director and other GCA/GCIAG executives.

Communication and Coordination:

- Organize and moderate weekly departmental meetings.
- Communicate feedback from the RA team to the Director and other stakeholders.
- Coordinate RA team to work with QA and Marketing teams to ensure updated QMS and regulatory compliance of marketing promotional materials.

Operational and Vendor Management:

- Support the Director of Regulatory Affairs in vendor relationship management and evaluation of proposals prior to Director approval.
- Work with Legal to ensure NDAs with third parties are up to date.
- Manage the cross-functional team responsible for the preparation of dossiers for regulatory submission, overseeing documentation formatting and maintenance within the documentation management system.

REQUIREMENTS

- A minimum of a bachelor’s degree in a science field required.
- Experience in Management and Regulatory Function in Pharma, Device or Healthcare
- License/Certification in Healthcare Professions optional but not required.
- Experience in Management and Regulatory Affairs.
- US and Global Managerial and Regulatory experience, Leadership, P&L Experience.
- Experience with FDA and Other US regulatory bodies required.
- Technology: Microsoft Office Suite, Chemgees, Salesforce, SAP

SALARY& BENEFITS

- $90,000-$120,000
- Comprehensive health benefits and 401K

#LI-JACUS #LI-US #countryUS

会社説明