Manager Regulatory Affairs

For more than 20 years, AlloSource's allografts have been the biologic solutions our surgeon customers use to deliver better care to their patients. As one of the largest and most respected nonprofit tissue banks in the United States, AlloSource develops, processes and distributes over 200 types of life-saving and life-enhancing allografts for use in a variety of medical procedures. Our commitment to honoring the gift of tissue donation motivates us to develop innovative allografts and lead the way in cellular and tissue therapies.

Summary:

To ensure that the regulatory requirements and company organizational goals are effective and in compliance. Provide expertise and guidance regarding domestic and international regulatory and quality requirements needed to meet product development projects, complaints, adverse reactions/events, field actions, regulatory reporting, internal and external auditing, document preparation, performance metrics and review of certain controlled documents. This position also provides guidance to AlloSource customers and AlloSource personnel.

Essential Duties and Responsibilities:

1. Develop, implement, and maintain procedures in support of regulatory compliance.
2. Assist with the development and implementation of regulatory strategies for existing, new and modified products.
3. Provide review and approval of product and process changes, as required, to ensure compliance with regulatory requirements.
4. Assist in developing and documenting sound regulatory decisions and justifications and advising organization on impact of changing regulations. Interpret product, policy and process changes to ensure compliance with regulatory requirements.
5. Assist with the creation and maintenance of regulatory documents and claims, and up-to-date (regulatory changes, business changes, new indications) labeling for products.
6. Review and approval of labeling and marketing collateral to ensure substantiation of claims, adequate information, and cautions/warnings are present and that all labeling is in conformance to regulatory requirements in accordance with Federal, state, and other applicable regulatory and quality requirements.
7. Assist with the timely preparation and submission of domestic regulatory submissions (pre and post market), and submission of Technical Files and/or international regulatory submissions, as well as internal regulatory file documentation, ensuring they meet appropriate standards and content requirements.
8. Oversee Complaint Handling, Adverse Reaction/Event Reporting, Deviation reporting, Recall, and Regulatory License/Registration systems.
9. Oversee internal audit system (Schedule, create checklist, communication, opening meetings, conduct audits, closing meetings, creating audit report, maintain internal/external audit files and records, and overseeing corrective actions.)
10. Host customer audits (plan, document and act as primary contact) and respond to audit findings.

11. Ensure completion of customer quality/regulatory surveys, maintain survey files.
12. Develop/provide reports for applicable quality metrics.
13. Oversee regulatory audits & responses in cooperation with, Regulatory and Quality Leadership
14. Provide guidance to staff in Regulatory and inspection matters.
15. Assist as a resource in Regulatory and Quality department planning and budgeting.
16. Adhere to and promote proper practices and techniques which are consistent with current operating procedures, training requirements, safety practices and company policies

Requirements:

- Bachelor's degree
- Regulatory Affairs Certification (RAC)
- 5-7 years regulatory/quality experience in an FDA regulated industry in the medical product space (ex: tissue banking, medical device, biologics or pharmaceutical).
- 5 years of personnel management experience in an FDA regulated environment in the medical product space.
- Previous experience preparing and submitting regulatory product submissions (i.e. TRG, 510(k), PMA, IND, BLA).
- Previous experience in a position that required multi-department interactions.
- Previous auditing experience (participation in, or management of internal audits, regulatory audits, supplier audits).

Preferred Experience:

- Bachelor's degree in Scientific or technical field.
- Preferred experience shall include direct experience in all aspects of Quality Systems and Regulatory Affairs, and indirect experience with related business functions (operations/manufacturing, research & development, marketing & sales).
- Knowledge of and experience with Risk Management systems [ISO 14971]
- Knowledge of and experience in managing Medical Device Quality Systems [ISO 13485, 21 CFR 820]
- Knowledge of and experience in managing Biologics [21CFR 210/211] Quality Systems.
- Knowledge of and experience creating and utilizing process maps.

TO APPLY:

Please visit www.allosource.org and click on "careers", then "opportunities". Complete your application and submit a resume for consideration

For consideration you must apply online, submit a current resume and meet the minimum requirements. All offers are contingent upon a background check, drug screen and other contingencies may apply depending upon the position. Candidates within a 50 mile radius of the hiring zip code may receive first consideration. If you require special accommodations, please contact us at 720-873-0213.

Equal Opportunity Employer/Veterans/Disability

AlloSource uses E-Verify to confirm the employment eligibility of all newly hired employees. To learn more about E-Verify, including your rights and responsibilities, please visit www.dhs.gov/E-Verify.