Regulatory Affairs Specialist - International

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:

The Regulatory Affairs Specialist, International is responsible for overseeing the domestic and international registrations. The position also supports regulatory submissions and maintains regulatory file documentation. Independent decisions are limited to the RA Specialists areas of expertise and input is sought from VP/Director, RA/QA and subject matter experts as necessary. Assists with internal audits, regulatory and customer audits.

Essential Duties and Responsibilities:

- Prepares and submit International Distribution registration dossiers and licensing requirements by managing certifications and licenses for International customers.
- Research and analyze government requirements, develop and compile documentation in support of new registrations.
- Conduct, compile and develop documentation in support of International distribution (e.g. Donor records, Certificate of Conformance and other information pertinent to local requirements and shipments.)
- Assist with Corrective and Preventive Actions, Nonconformance investigations, complaints and adverse reaction/event investigations or other failure investigations.
- Interact with internal and external customers & regulatory bodies and assist customers and regulatory audits as required.
- Create, organize and maintain International data repository for all submitted quality and customer documents.
- Assist and participate with International and Quality Systems/Regulatory projects.
- Adhere to and promote proper practices and techniques which are consistent with current operating procedures, training requirements, safety practices and company policies.

Requirements:

- High School diploma or equivalent
- 3-5 years' working in a regulated industry
- A working understanding of Quality systems, FDA regulatory requirements, and AATB Standards
- Previous experience in a position that required multi-department interactions
- Proficiency in Microsoft Office applications

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.

TO APPLY: Please visit www.allosource.org Select the position and submit your resume as well as a completed application to be considered for the position.