Quality Systems Auditor

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.

Compliance Statement
Must comply and ensure adherence with FDA, CGTP, OSHA, AlloSource SOPs, work instructions & procedures, proper practices and techniques, AATB standards, and applicable company policies, training requirements, safety practices and regulatory requirements that are applicable to the job responsibilities.

Summary
Maintain programs in support of the quality system, specifically related to internal auditing and customer audits for FDA regulations, AATB and ISO Standards. This includes participating in audits and maintaining audit documentation.

Essential Duties and Responsibilities:

1. Perform audits to ensure adherence to the annual internal audit schedule.
2. Execute internal audits as assigned.
3. Provides thorough, succinct, evidence based audit reports and notes compiled during audits.
4. Participate in customer audits as needed and respond internally to audit findings.
5. Provide assistance to Regulatory and Quality Management for applicable procedure writing, maintenance of accreditations and certifications.
6. Complete customer quality/regulatory surveys, maintain survey files.
7. Provide reports for applicable quality metrics.
8. Assist with regulatory body audits as required.
9. Assist with Supplier Quality audits as required.
10. Adhere to and promote proper practices and techniques which are consistent with current operating procedures, training requirements, safety practices and company policies.

Requirements:

- 7+ years regulatory/quality experience in an FDA regulated industry (ex. tissue banking, medical device, biologics, or pharmaceutical).
- 3 years direct auditing experience in an FDA regulated environment.
- Previous experience in a position that requires multi-department interactions.
- Proficiency in Microsoft Applications, specifically Excel, Word and Outlook
- Bachelor's degree
- In lieu of degree, 8 years working in a regulated industry with direct auditing experience.
- Auditor certification (ex. Certified Quality Auditor, Certified Biomedical Auditor, Certified Lead Auditor).

Preferred Experience:

- Knowledge of and experience in auditing Medical Device Quality Systems [ISO 13485, 21 CFR 820]
- Bachelor's degree in a scientific or technical field.

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.

EOE/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.