Sr Quality Systems Specialist

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 Sr Quality System Specialist will serve as the Quality Subject Matter Expert and Trainer for specific processes within the Quality System. Makes decisions based upon knowledge and experience, with regulatory compliance and the integrity of AlloSource at the forefront of consideration. They oversee, manage, and maintain a specific process within the Quality System (i.e., CAPA, NC, Change Control, Document Control, Training Compliance, Quarantine, Equipment Management), and provide guidance and advice to AlloSource personnel related to that system. Identifies and resolves training discrepancies, and evaluate, recommend, and implement improvements for the department's processes, based on standards & regulations, change controls, corrective & preventive actions, and process improvement projects.

Essential Duties and Responsibilities:

1. Administer AlloSource's Quality Management System (QMS) Process.
    a. Serve as the organization's system expert for representative system during internal and external audits.
    b. Perform regular audits of Quality System Process to ensure system processes are operating in accordance with controlled procedures
    c. Initial point of contact for end users in terms of document control, training, system functionality, process set up requirements, and resolution of discrepancies.
    d. Review submissions to Quality Management System (QMS) for spelling, punctuation, formatting and assure appropriate review and approval.
    e. Perform system configuration updates
2. Manage and maintain updates to the system.
    a. Ensure data integrity and document/file accessibility.
    b. Ensure data adheres to company policy and meets regulatory requirements.
    c. Approve and perform system configuration administrative updates
    d. Draft detailed validation testing protocols outlining system requirements, when needed.
3. Serve as the technical expert for a specific Quality Management System process.
    a. Provide a central contact point for all document control issues, support, and ongoing management of the system.
    b. Effectively train, mentor and advise all company personnel on the specified Quality Management System.
    c. Address end user questions promptly with a professional and courteous demeanor.

d. Confer with document owners and department managers to establish process set-up requirements and resolve discrepancies as needed.

4. Manage and maintain specified QMS related policies and procedures.
   a. Establish and implement policies and procedures and update them as they evolve.
   b. Communicate issues related to the QMS to management as needed.
   c. Provide periodic productivity and compliance reports to Management, and compile/analyze data presented at Quarterly Management Review meetings.
5. Serve as the Business Process Owner of the specified Quality Management System.
   a. Oversee and implement improvements/upgrades to the system
   b. Evaluate and enhance current processes in all areas of the company for improved efficiency, automation and increased productivity.
   c. Lead correspondence of the automated Quality Management Systems (SmartSolve) with the service provider.
   d. Create User requirements specifications
   e. Prepare and execute validation testing protocols
   f. Adhere to and promote proper practices and techniques which are consistent with current operating procedures, training requirements, safety practices and company policies.
   g. Oversee execution of validation testing and analyze results of pre-determined testing criteria.

Requirements:

- Bachelor's degree in biological sciences, or similar field.
- In lieu of degree, 7 years' working in an FDA regulated industry.
- Successful completion of AATB Certification required within one year of accepting role.
- 5 years' experience working with quality records in an FDA regulated industry.
- 3 years' working with specified QMS.
- 3 years' technical writing experience.
- Advanced proficiency in Microsoft Applications, specifically Excel, Word and Outlook.

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.