| LifeSource<br>ORGAN, EYE AND TISSUE DONATION<br>2225 West River Road North<br>Minneapolis, MN 55411<br>1.800.24.SHARE | POSITION DESCRIPTION | |
|---|---|---|
| | PD-0000 | Rev 5 |
| | Quality System Program Administrator | |

**DEPARTMENT:** Quality and Regulatory Affairs
**STATUS:** Exempt; Salaried
**EXPOSURE RISK:** Category III
**SALARY GRADE:** TBD
**REPORTS TO:** Compliance Manager
**SUPERVISES:** N/A

**GENERAL JOB FUNCTION**

The Quality System Program Administrator is responsible for coordination of clinical and non-clinical audits and supplier qualifications to assess compliance with internal processes, procedures and applicable federal, state, accreditation, and regulatory requirements. Collaborate with leaders on defining program priorities, strategy, and schedule ensuring successful and timely execution. Maintains knowledge of compliance industry standards, guidelines, accreditation and regulatory requirements, including audit tools, controlled documents and operational processes. Ensures thorough documentation within Quality Management System software program. Monitors and facilitates review of effectiveness and completion of corrective and preventive actions (CAPA). Aligns daily activities with the strategic and operational goals of the organization.

**JOB DUTIES AND RESPONSIBILITIES**

**Develop, coordinate and facilitate quality compliance audit program to verify execution and effectiveness of processes and procedures to meet internal compliance, accreditation or regulatory standards.**

1. Coordinate the planning, execution, and documentation of onsite and desktop audits, including internal, external and third party regulatory, accreditation or customer audits, for clinical and non-clinical areas.
    a. Specifically, conduct routine internal audits, including Donor Risk Authorization Interview (DRAI) audit and Authorization audit.
2. Effectively manage and utilize the audit module of the Quality Management System (QMS) software.
    a. Create, develop and manage audits, audit schedules, audit checklists, and audit reports.
    b. Develop checklists and documents for collection of evidence-based findings during audits in compliance with customer, local, state and federal regulations and accrediting agencies.
    c. Ensure final approval, documentation, and communication of audit reports and findings.
    d. Reviews documentation of corrective and preventative action (CAPA) responses to audit findings.
    e. May assign tasks and activities to organize, track and trend all audit findings and follow-up.
3. In collaboration with auditee, coordinates schedules and timelines, conducting pre- and post- audit meetings.
4. Follow up with auditee for adequate, accurate and timely completion of CAPA.
5. Conduct verification audits of implemented CAPA's ensuring execution and maintenance are compliant with requirements.
6. Serve as the subject matter expert regarding audit program management, assisting with continued development and education for all relevant leaders and team members on the audit process to ensure continuous competency, including use of QMS audit module.
7. Engage and provide written and statistical reports of audit program for defined meetings, as appropriate.

**Develop, coordinate and mange supplier qualification program to verify qualifications to meet accreditation or regulatory standards.**

1. Create, develop and manage supplier setup, qualifications, documentation and reports within the supplier module of the Quality Management System (QMS) software. Within QMS, may assign tasks and activities to organize, track and trend supplier performance and program requirements.
2. Participate in the planning, implementation, and/or management of supplier qualifications and performance to include both clinical and non-clinical areas of the organization.

3. Work cross departmentally to ensure all suppliers and contractors are deemed qualified per internal policies and regulatory requirements.
4. Serve as the subject matter expert regarding supplier qualification management program, assisting with continued development and education for all relevant leaders and team members on the audit process to ensure continuous competency, including use of QMS audit module.
5. Manage initial and ongoing on-site or self-reported supplier evaluation and assessments to ensure compliance with relevant LifeSource, regulatory, and accreditation requirements.
6. Engage with leadership if supplier evaluation or performance is found to be unacceptable. May assist with recommending a proposed corrective action plan, or follow up, as necessary.

**Engage as a subject matter expert (SME) on quality system processes and procedures including applicable federal, state, accreditation, and regulatory requirements.**

1. Routinely evaluate, propose recommendations for changes to leadership regarding QMS software product enhancements.
2. Remain apprised of advancements and changes within the industry. Assist with the establishment and implementation of new processes and procedures in response to regulatory or other changes affecting the position or work processes.
3. Engage, in collaboration with leadership, in the systematic evaluation of processes, analysis of performance metrics and other improvement activities. Propose and recommend opportunities for ongoing development initiatives or process enhancements in alignment with strategic goals.
4. Maintain and apply an understanding of areas of regulation as appropriate, including Organ Procurement Transplant Network (OPTN), United Network of Organ Sharing (UNOS), Centers for Medicare & Medicaid Services (CMS), America Association of Tissue Banks (AATB), Food and Drug Administration (FDA), Eye Bank Association of America (EBAA) and Association of Organ Procurement Organizations (AOPO).
5. Identify areas of risk and assist leaders in the integration and assurance of compliance above mentioned standards.

**STANDARD RESPONSIBILITIES**

1. Perform work while demonstrating a commitment to excellence and performance improvement.
2. Update clinical and administrative documentation, including electronic systems, with accurate, real-time, appropriate information according to established practices and procedures.
3. Represent LifeSource in a professional manner with both internal and external customers, ensuring professional appearance and communication.
4. Participate in all appropriate meetings, in-person, on-site, or remote, as defined by leader.
5. Routinely share feedback, solutions and ideas to leadership, including identification of training needs.
6. Exhibit outstanding clinical, customer service and collaboration skills as required by position.
7. Maintain confidentiality and respect of information obtained within purview of position, as defined by policy and procedure expectations and in accordance with HIPAA.
8. Demonstrate LifeSource Values in work behaviors and actions.
9. Actively participate on assigned committees, work groups and project teams.
10. Execute job responsibilities in accordance with established Standard Operating Procedures (SOPs), Policies (POL), and practices as trained.
11. Perform other duties as required and assigned by leader.

**QUALIFICATIONS**

1. Requires a Bachelor's degree in Business or Health Sciences and three years of healthcare audit or Quality Systems/CAPA experience or equivalent education and experience.
2. Requires certification as a Quality Auditor or ability to obtain within one (1) year of entry in the position. Once certified, you must obtain the required continuing education or recertification credits/process.
3. Prefer previous experience working with a Quality Management System software program.
4. Demonstrated ability to provide a high level of customer service to internal and external customers with the ability to develop and connect with people quickly.
5. Proven self-directed, motivated contributor with a strong initiative and ability to function autonomously, establish priorities, meet timelines and deadlines and work effectively within a team environment.
6. Ability to build, maintain, motivate, influence, and achieve cooperation with both internal and external relationships.
7. Must be organized, detail oriented, and have excellent critical thinking and analytical skills.
8. Strong verbal and written communication skills, including ability to identify opportunities for process improvement by developing proposed solutions to identified areas of improvement.
9. Strong working knowledge of Microsoft Office applications.
10. Demonstrated ability to exhibit a high degree of quality, integrity, and honor confidentiality of appropriate information including, but not limited to, personal team member data, organizational operations or work processes, donor and donor family information, contributor details, any financial information and medical or protected health information (PHI) in accordance with HIPAA.
11. Proven skilled and competent in using technology-based devices and mobile tools such as personal computers and related software, electronic medical record systems, mobile phones, and mobile printing devices.

**WORKING CONDITIONS**

1. Able to work a minimum of 40 hours per week with schedule adjusted to accommodate organizational needs.
2. Affected team member in Category III never or rarely have exposure to bloodborne pathogens and do not have a potential for this exposure or handle materials that could spread infection (less than one opportunity per month). Additionally, they rarely interact with staff in patient or donor areas in a hospital or clinic setting while performing their assigned job duties.
3. Ability to lift up to 20 pounds occasionally.
4. Must be able to follow and successfully complete category immunization, health screening and background check requirements.

**Team Member Statement of Acknowledgement and Understanding**

Acknowledgement of this job description is performed electronically via Q-Pulse—the LifeSource document control system. A team member's electronic signature will represent the following statement of understanding:

*I acknowledge that I have received and reviewed the job description for my position and I feel that I can meet the requirements with or without reasonable accommodations. I understand that this job description is intended to describe the general content and requirements of the job and that it is not an exhaustive list of all duties, responsibilities and requirements of this position. Additionally, I understand the general description of the expectations related to work hours and absences, attached herein, are subject to change based on department and organizational requirements. I understand that LifeSource has the right to revise this job description at any time.*

**The following is a general description of the expectations related to work hours and absences. This is subject to change based on department and organizational requirements.**

## POSITION EXPECTATIONS

**Job Title:** Audit and CAPA Management Coordinator
**Reports To:** Compliance Manager
**Exemption Status:** Exempt; Salaried

## WORK

**Work Day:** Monday – Fridany
**Hours:** 0800-1700
**Lunch/Breaks:** Self-directed
**Overtime:** N/A
**On-Call:** N/A
**Flexible Hours:** Yes
**Flexible Location:** Yes
**Weekends:** N/A
**Travel:** TBD
**Mandatory Meetings:** Department & All Team Meetings
**Shift Relief:** N/A

## ABSENCE

***Planned Absence*** *(Vacation, Holiday, Leave of Absence, etc.)*
**Short-term:** Submit via HRIS & coordinate coverage within team.
**Long-term:** Submit via HRIS & coordinate coverage within team. Hire temp help as necessary.
***Unplanned Absence*** *(Injury, Illness, Leave of Absence, etc.)*
**Short-term:** Submit via HRIS & coordinate coverage within team.
**Long-term:** Submit via HRIS & coordinate coverage within team. Hire temp help as necessary.

## COMMENTS