LifeSource
ORGAN, EYE AND TISSUE DONATION
2225 West River Road North
Minneapolis, MN 55411
1.800.24.SHARE

POSITION DESCRIPTION

PD-0111 | Rev 4

Regulatory Compliance Specialist

DEPARTMENT: Quality and Regulatory Affairs
STATUS: Exempt; Salaried
EXPOSURE RISK: Category III
SALARY GRADE: 70
REPORTS TO: Manager of Quality and Regulatory Compliance
SUPERVISES: N/A

GENERAL JOB FUNCTION

The Regulatory Compliance Specialist is responsible for:

- Coordinating, developing, and executing assigned clinical and non-clinical audits in a highly regulated organ, tissue, and eye donation environment.
- Collaborating with appropriate leaders to schedule and prioritize audits and assess audit outcomes to determine any needed changes to ensure ongoing regulatory compliance.
- Assessing donor record and data submission compliance against internal and external requirements.
- Facilitating and investigating defined donor inquiries and preparing responses for leadership review and submission.
- Developing and maintaining an understanding of current and proposed regulations applicable to organ, tissue, and eye donation.

JOB DUTIES AND RESPONSIBILITIES

Compliance Audits—*Develop, coordinate, and facilitate compliance audits 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 assigned audits:
    a. Coordinate the organization's audit program and audit schedule via the organization's established Quality Management System (QMS) software, including audit checklist and report development.
    b. Coordinate the timely execution and appropriate documentation of scheduled audits.
    c. Document the appropriate outcome and audit findings and submit final audit reports to area leader(s) for review.
    d. Review responses to audit findings for appropriateness and completeness.
    e. May be assigned certain tasks and activities to organize, track and trend audit findings and follow-up.
2. Monitor changes to regulatory and accreditation requirements and notify appropriate leaders via a systematic and timely process.
    a. Collaborate with leaders to update organizational policies and procedures to meet new and updated regulations and standards.
3. Assist in preparation efforts and provide real-time support for routine on-site regulatory and accreditation (third-party) onsite inspections.

Data Submission Verification—*Perform verification of time-sensitive data submissions on assigned donor records to ensure accuracy and adherence to regulatory reporting and quality service requirements.*

1. Review assigned donor records to ensure compliance with regulatory agencies requirements.
2. Monitor accuracy of donor information submitted in the Deceased Donor Feedback (Feedback) and Deceased Donor Registration (DDR) forms, in accordance with Organ Procurement and Transplantation Network (OPTN) policies.
3. Facilitate investigations related to Potential Disease Transmissions (PDT) and submit required information to the OPTN system according to defined policies.

   a. Evaluate donor records for documentation of infectious disease process, autoimmune disease, communicable disease, and other medical conditions for any potential disease transmission.
4. Verify defined donor charts to ensure data collection processes are consistent, repeatable, and appropriate.
5. Obtain and distribute applicable information and reports to/from other organizations, as appropriate (e.g., transplant centers, tissue and eye processors, regulatory agencies, research organizations, etc.)
6. Review organ tracking data and collaborate with the Organ Services Leadership Team to update and/or develop organizational policies and practices that improve organ utilization.
   a. Collaborate with process improvement and subject matter experts to identify areas where process and policy changes would improve efficiency and compliance.
   b. Collaborate and support regulatory education and good documentation efforts that improves process efficiencies, outcomes, and donation recipient safety.

Donor Inquiries, Process Deviations, and Patient Safety—*Coordinate appropriate communication and follow through with applicable regulatory and donation agencies related to process inquiries, deviations, and patient safety concerns.*

1. Monitor and report compliance performance per OPTN organ allocation policies and data submission requirements.
2. Communicate planned allocation deviations to the United Network for Organ Sharing (UNOS).
3. Respond to OPTN inquiries, including appropriate follow up and closure.
4. Coordinate the documentation and distribution of relevant donor information received post-case and subject to timely communication to relevant transplant centers (TXCs), organ procurement organizations (OPOs), and other applicable agencies.

STANDARD RESPONSIBILITIES

1. Perform work while demonstrating a commitment to excellence and performance improvement.
2. Update appropriate 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 combination of education and experience equivalent to 5-7 years of healthcare, clinical or regulatory environment experience.
2. Knowledge or competency in organ procurement and Organ Procurement and Transplantation Network (OPTN) regulations strongly preferred.
3. Self-directed, motivated contributor with ability to function autonomously, manage multiple projects simultaneously, set priorities, execute timely follow through and meet deadlines.

4. Effective communication and interpersonal skills, effective at establishing rapport and working relationships with leaders, peers, and vendors.
5. Meticulous and highly organized with a desire to improve processes, take initiative and solve problems.
6. Excellent critical thinking and analytical skills to confidently execute reasonable and sound decision making.
7. 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.
8. Strong working knowledge of Microsoft Office applications.
9. Proven skilled and competent in using technology-based tools such as personal computers and related software, mobile devices, and electronic medical record systems as appropriate for position.

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 OSHA Exposure Category III never or rarely have exposure to bloodborne pathogens and do not 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 and carry objects up to 40 lbs.
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: Regulatory Compliance Specialist
Reports To: Manager of Quality and Regulatory Compliance
Exemption Status: Exempt; Salaried

WORK

Work Day: Monday – Friday
Hours: 0800 – 1700
Lunch/Breaks: Self-directed
Overtime: N/A
On-Call: N/A
Flexible Hours: Yes
Flexible Location: TBD
Weekends: N/A
Travel: N/A
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 temporary 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 temporary help, as necessary.

COMMENTS