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

POSITION DESCRIPTION

PD-0055 | Rev 4

Document Control and Quality Assurance Specialist

DEPARTMENT: Quality and Regulatory Affairs
STATUS: Non-exempt; Hourly
EXPOSURE RISK: Category III
SALARY GRADE:
REPORTS TO: Quality Systems Manager
SUPERVISES: N/A

GENERAL JOB FUNCTION

The Document Control and Quality Assurance Specialist is responsible for the control, organization, updating, distribution and maintenance of all documents within the Quality Management System (QMS) Documents module in accordance with organizational policies and regulatory requirements. Execute ongoing document control system to ensure documents maintain compliance with all internal and external regulatory requirements including creation, naming convention, timely revisions, accuracy, completeness, approval, activation and distribution. Coordinate a systematic health information management program for all donor charts to facilitate a timely, efficient, and effective quality assurance review. Engage in supporting applicable quality assurance projects related to federal, state, accreditation and regulatory requirements of donor records. Align daily activities with the strategic and operational goals of the organization.

JOB DUTIES AND RESPONSIBILITIES

Maintain controlled documentation accuracy, distribution, access, and format in accordance with the established distribution lists, workflows, and plans.

1. Coordinate and manage the process for creating and revising documents housed within QMS, including Forms (FORM), Standard Operating Procedures (SOP), Policies (POL), Guidance (GUI), Position Descriptions (PD), Safety Data Sheets (SDS), Work Instruction (WI), Regulatory and Accreditation, Customer Controlled Documents and Proprietary Documents for all departments across the organization.
    - Review all submitted documents against set criteria and organizational standards including accuracy, completeness, clarity, approvals, and release authorization.
    - Execute the established, consistent naming convention to ensure accuracy and expedient retrieval. Ensure any hard copies produced are classified/tagged exactly as their electronic counterparts.
    - Process revisions to controlled documents in the same manner as the original documents and superseded documents, ensure change documentation is identified as such.
    - Verify that approved documents adhere to format requirements; activate and distribute as defined.
2. Coordinate with leaders and document owners for appropriate distribution process for new records and changes, including review only or acknowledgement.
3. Monitor program correspondence to ensure that transmitted documents have been received and that document requiring response are completed in a timely manner, notifying leadership as appropriate.
4. Work across the organization to ensure timely completion of periodic reviews, updating, revising, and assigned action items.
5. Provide training and technical support to the QMS program users, including the overall functionality of the document control system.
    - Create and revise procedures, work instructions, and templates for QMS document control use, as needed.
6. Maintain an active role in system and process level improvements for the document control function of the Quality Management System (QMS).

Coordinate a systematic health information management program for all LifeSource donor charts working closely with the Quality Assurance Coordinators to facilitate timely, efficient, and effective quality assurance review.

1. Address quality assurance correspondence by responding and/or orwarding to respective quality team members, or facilitating action and follow up with processors, partners or other stakeholders.
2. Facilitate retrieval of final information or reports from partners, logging and uploading to electronic medical record (EMR), subsequently distributing information to appropriate processor stakeholders.
    a. Ensure requested confidential medical documentation is obtained, including culture, serology, pathology, toxicology and autopsy reports.
    b. Perform donor chart data entry, document upload to EMR and other applicable databases.
3. Maintain an efficient donor record filing system within a secure environment, including the timely filing of required donor documentation.
    a. Prepare, support and ensure timely execution of all organ, eye and tissue donor chart closure, in collaboration with quality assurance team.
    b. Extract all required medical documents from EMR and compile into final donor record.
    c. Facilitate applicable donor record prep and documentation for off-site storage and archiving.
4. Ensure professional and collaborative communication, maintaining confidentiality, with partners and customers to manage and resolve inquiries or information requests, within the quality assurance process.

Engage in developing an understanding of applicable quality assurance federal, state, accreditation and regulatory requirements for donor records.

1. Assist with external and third-party audits as appropriate, which may include supplier, customer, accreditation, and regulatory audits.
2. Support and collaborate with quality assurance team on special projects as needed.
3. As appropriate, maintain and apply an understanding of areas of regulation, 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).

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 education and experience equivalent to 5 years of healthcare, quality assurance, or medical record experience.
2. Prefer previous experience working with a Quality Management System software program.
3. 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.
4. 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.
5. Ability to build, maintain, motivate, influence, and achieve cooperation with both internal and external relationships.
6. Must be organized, detail oriented, and have excellent critical thinking and analytical skills.
7. Strong verbal and written communication skills, including ability to identify opportunities for process improvement by developing proposed solutions to identified areas of improvement.
8. Strong working knowledge of Microsoft Office applications.
9. 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.
10. 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.