

Regulatory Affairs Supervisor

Job Description

Miracles In Sight seeks a full time Regulatory Affairs Supervisor. The Regulatory Affairs Supervisor assures Eye Bank quality by establishing and enforcing quality standards, competency testing and the delivery of safe and compliant eye tissue for surgery. Monitors and ensures company compliance with Federal and Industry regulations and continuously looks for areas of operations to improve. Reports to the VP Regulatory & IT and is part of the Regulatory Affairs Team.

Essential Duties and Responsibilities

REGULATORY

- Safeguard the tissue supply of the MIS by establishing and maintaining quality system programs, ensuring the organization's compliance with medical standards and applicable state and federal regulations and MIS's internal quality control programs
- Uses FDA rules, EBAA Medical Standards, and State and local regulations as guidance for creating the quality program
- Manages the Corrective Action/Preventative Actions program
- Establish tissue documentation and record creation protocol by writing and updating quality assurance SOPs in the SOP manual.
- Creates, authorizes critical forms for use in eye bank operation (document control)
- Develop and implement key Quality System performance metrics.
- Advises the Medical Director concerning adverse reactions, subsequent investigations and outcomes
- Interface directly with inspectors and auditors when required
- Creates corrective actions if inspectors or auditors find deficiency in the Quality program
- Establish standards for the disposition of tissue by continuously evaluating methods and procedures.
- Ensure customer satisfaction and addresses complaints by enforcing quality assurance policies and procedures, and government regulations, and by collaborating with other members of management to continuously improve quality systems.

TRAINING

- Develop a solid understanding of technology and quality systems services in order to provide informed answers to management, employees, hospital staff and other affiliated organizations.
- Collaborate with other directors to establish, standardize, and document all aspects of staff training, certification, and continuing education.
- Carry out annual OSHA program that complies with all safety regulations, blood-borne pathogen standards, hazardous material training and on the job injury reporting.

Job Qualifications

- Knowledge of GTPs or GMPs
- Ability to understand compliance regulations from FDA, etc.
- Interpret and apply federal and industry rules to actual eye banking practice
- Maintain professional and technical knowledge by constantly reviewing industry publications, networking with other transplant agencies attending educational workshops as requested by management
- Must be aware of the role they play in patient safety as defined by EBAA and FDA rules as well as MIS SOPs
- Possess excellent computer skills
- Possess excellent writing and communication skills
- Knowledge of medical and ophthalmic terminology
- Demonstrate exceptional customer service
- Ability to interact with co-worker within and outside of the department as well as outside agencies
- Ability to effectively present information and respond to questions
- Ability to set priorities and manage multiple priority tasks
- Contribute to the success of the department by working as a team member and demonstrating the flexibility to accomplish a common goal
- Appropriate dexterity to use office equipment
- Ability to cope with issues pertaining to death is essential
- Ability to maintain a valid driver's license
- Be a self starter and perform work independently

Education

Bachelor's degree in Biology or Physical Science, Health Science, Statistics or Math preferred. Appropriate experience in regulatory or quality may be substituted for education. Thorough knowledge of ocular anatomy and physiology and disease processes are needed to understand aspects of donor safety.

Benefits

- Medical, Dental, Vision, HSA, Retirement, Life, AD&D
- Opportunity for advancement
- Excellent Training
- Rewarding work