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Title: Manager of Quality and Compliance
Reports to: Director of Quality and Compliance
Effective Date:

Position Summary: The duties and responsibilities of the Manager of Quality and Compliance, is to serve as the key messenger in establishing a strong line of communication between the Office of Ethics & HIPAA Compliance, the laboratory, field organization, and as the key advocate in the administration of the organization's Compliance Program under the direction of the Director of Quality and Compliance.

Ensures that all functions of the laboratory are conducted in a manner that follows all regulatory, accreditation and compliance requirements. This includes safety and quality assurance, proper employee training and compliance with necessary rules and regulations.

Collaborates with management, support services and clinical departments to meet designated standards and compliance regulations.

Job Specific Duties and Responsibilities:

- Provide department support through data analysis and special projects assigned by laboratory leadership
- Participate in compliance and quality audits for the organization
- Document and review actions to error corrections
- Work in collaboration with management, client services, and laboratory departments to meet designated organizational standards
- Report quality documentation as appropriate to laboratory leadership and departments at an appropriate frequency
- Assist in maintenance of the Quality Management Plan and Compliance Plan for the organization
- Maintain knowledge of laws and regulations via educational webinars, readings and conferences to ensure the laboratory is preventing illegal and unethical conduct
- Maintain communication with outside legal groups in difficult legal situations
- Communicate with clients and customers as needed
- Supports the document control for the laboratory utilizing the laboratory document control system
- Assist with compliance investigations and implementing compliance regulations for the laboratory
- Assist with other duties when necessary

Qualifications:

Required:

- Bachelor's degree with a science related background preferred
- 2+ years' experience within a clinical laboratory setting
- Lean Six Sigma certification or experience preferred
- Previous leadership experience preferred

Knowledge, Skills, and Abilities:

- Ability to problem solve issues
- Strong attention to detail and organizational skills
- Knowledge of laboratory compliance regulations
- Effective project management skills
- Ability to effectively implement change in a fast-paced environment
- Proficient with Microsoft Office applications
- Positive communication skills
- Excellent customer service skills

Who We Are:

Helix is a value-based, state-of-the-art clinical laboratory on a mission to elevate the lab space through compliance, high ethics, innovation and a best in class client experience. Helix incorporates the latest technology and methods to provide comprehensive diagnostics including toxicology testing, pathogen detection, blood testing and Pharmacogenomics (PGx) testing.

Expected Use and Disclosure of Protected Health Information:

Employees in this position are expected to have access to protected health information and other confidential business information from throughout the organization as is needed to fulfill their responsibilities in evaluating and reducing risk to the organization. No protected health information will be disclosed outside the organization unless specifically required by state or federal law.

*This document is intended to describe the general nature and level of work performed and the requirements of the position. It is not intended to serve as an exhaustive list of all duties, skills and responsibilities of personnel so classified; nor is it intended to limit the right of any leader to assign or direct employees under his/her direction.