DYNEX TECHNOLOGIES	**Document type:** **Job Description**	**Document Number:** **JD142**
Job Title: Quality Assurance Manager	**Revision** **A**	**Authored Date:** **2019-06-19**

Department: Quality Assurance

FLSA Status: ☒ **Exempt** ☐ **Non-Exempt**

Job Summary: Responsible for developing, implementing, monitoring and maintaining Dynex's quality programs. Provide guidance and training to all employees on Dynex Quality & Regulatory Initiative, GLP's, GMP's, ISO, product development, manufacturing, and service quality programs. Provide support on ongoing development, implementation and maintenance of Dynex quality assurance systems and practices.

The quality assurance manager job description entails coordinating and supervising activities required to meet quality standards for the development, manufacture, and service of In Vitro Medical Devices. The role involves monitoring and advising the performance of a quality management system, producing data, and measuring quality operations against set standards. Provide guidance and training to all employees on Dynex Quality & Regulatory Initiative, GLP's, cGMP's, ISO.

Provide leadership and direction to ensure achievement of business goals and objectives by ensuring distribution of quality products as well as compliance with all applicable local, state and federal agencies and regulatory bodies.

Essential Functions:

The Quality Manager leads the Quality Assurance Department to assure product compliance with the Quality Management System by performing the following duties personally or through Employees/QA Inspectors:

- Hosting QA Audits as needed.
- Carry out supervisory responsibilities including training employees, planning, assigning, directing work and appraising performance.
- Communicate effectively with customers on quality related problems.
- Manages all quality activities to ensure product sustainment meets Quality Management System requirements and customer quality expectations.
- Develop, lead and execute a quality strategy, ensuring that the quality strategy is appropriate and effective in meeting the business needs.
- Administer and manage all aspects of an effective DYNEX Quality Management System.
- Ensures that the requirements of 21 CFR part 820 and Part 803 and ISO 13485 standards and any other applicable government or international standards are implemented and maintained.
- Oversees the quality and regulatory functions responsible for complaint handling, and product improvement.

- Oversee all internal and external audit activities (FDA, ISO, Supplier Quality, etc.).
- Work with executive staff to achieve DYNEX's mission, vision and objectives.
- Communicate and drive the overall QA vision, quality goals and achievements to all employees as well as executive staff on a regular basis.
- Lead the development and implementation of quality procedures, work instructions and forms to coincide with operational and process related changes to daily work flow.
- Oversee all inspection activity including calibration and finished goods.

Supervisory Responsibilities: QA staff and QC Engineer (currently 4 staff).

Success Factors: Strong communication skills. Ability to work independently with little supervision.

Minimum Qualifications / Education: Bachelor's Degree in a scientific discipline. Specific knowledge of International Standards, ISO and FDA regulations with a minimum of 8 years of experience in a medical device industry.

Computer Skills: Proficiency in MS Office.

Work Environment: Office.

Physical Requirements: Must be able to meet National Institute for Occupational Safety & Health (NIOSH) Standards.

EMPLOYEE ACKNOWLEDGEMENT

I, _____, acknowledge review of this job description.
(Employee's Name - PRINT Name)

_____ **Date:** _____
Employee's Signature **YYYY-MM-DD**

_____ **Date:** _____
Supervisor's Signature **YYYY-MM-DD**