Exempt Job Description

Position Title: **Manager, Quality and Regulatory**
Department: **QA/RA**
Effective: **September, 2018**

Position Summary:

Develops, coordinates, and implements quality management programs required for the development, approval and successful manufacture of products. Leads the organization through the Quality System Regulation, 21 CFR 820, and the European quality management system standard, ISO 13485:2016 and oversees activities to assure successful certification audits as required. Monitors manufacturing, development and quality processes to ensure conformance and compliance with all FDA and applicable international regulations at Nexus-Dx, Inc. Leads domestic and international product registrations working directly with local customers and distributors. Manages corporate document control program and systems.

Education and Experience:

B.S. degree in a scientific discipline or equivalent experience with a minimum of eight years related experience in a medical device or in-vitro diagnostic field with instrumentation experience desirable. A minimum of 3 years in a supervisory/decision making role. Demonstrated proficiency with Quality Systems Regulation, 21 CFR 820 and ISO13485:2016 requirements. Experience improving and managing quality management systems. Must have proven managerial and interpersonal skills. Experience conducting internal and supplier audits, inspections of manufacturing facilities. Requires excellent verbal and written communication skills.

Essential Functions/Major Responsibilities:

- Leads the Quality organizations personnel.
- Designs, establishes, and implements a site quality management system, based on FDA and applicable international regulations.
- Manages the Corrective and Preventative Action Program.
- Designs and implements programs ensuring compliance with the IVD Directive as required.
- Monitors compliance with all FDA and applicable international quality management system regulations.
- Ensures compliance with all Quality objectives for all product development teams.

- Conduct Internal Audits and manages Internal Audit Schedule.
- Provides Metrics for Quality Monitoring/Management Review.
- Responsible for compliance with the company's quality system requirements through training and adherence to policies, procedures and processes.
- Provide regulatory and quality guidance to Operations and Product Development.
- Oversee processes involved in maintaining annual licenses, registrations, listings and patent information.
- Manages product Registrations, working directly with the Nexus EU Representative, customers and distributors.

Scope:

Provides direction to, and review of, subordinates to meet objectives and schedules and resolve technical problems. Receives assignments in the form of objectives and establishes goals to meet objectives. Works on problems of a diverse scope in which analysis of situations or data requires an evaluation of identifiable factors. Exercises judgment within generally defined practices and policies in selecting methods and techniques for obtaining solutions. May assist in developing and modifying functional area policies. Works within functional area budgets; develops schedules and performance requirements and ensures they are met.