QUALITY ASSURANCE AND REGULATORY AFFAIRS MANAGER

Employment Type: **Full-Time / Exempt**
Department: **Quality Assurance / 270**
Effective: **July, 2022**

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 In-Vitro Diagnostic Regulation (2017/746) and the European quality management system standard (ISO 13485:2016). Monitors manufacturing, development, quality, and regulatory processes to ensure conformance and compliance with all FDA and applicable international regulations at Nexus Dx, Inc.
Executes regulatory activities according to project plans to assure new products meet submission, approval and commercial launch goals. Related activities include compiling and writing FDA and IVDR reports as well as coordinating the completion of technical file requirements across multiple departments.
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 5-7 years related experience in a medical device or in-vitro diagnostic field; including 2+ years in Regulatory Affairs.
- A minimum of 3 years in a supervisory/decision making role. Demonstrated proficiency with Quality Systems Regulation, 21 CFR 820, IVDR 2017/746 and ISO13485:2016 requirements.
- Experience improving and managing quality management systems.
- Experience conducting internal and supplier audits, inspections of manufacturing facilities.
- Working knowledge of GMP, GLP, and GCP regulations as well as an understanding of the medical device product life cycle.

Essential Functions/Major Responsibilities:

- Ensures compliance with established policies and procedures.
- Provides guidance on compliance with regulatory requirements.
- Designs, establishes, and implements a site quality management system, based on FDA and applicable international regulations - IVD Regulation (IVDR).
- Support all Company initiatives as identified by management and in support of Quality Management Systems (QMS) and other regulatory requirements.
- Responsible for the management and administrative aspects of global regulatory submissions and life cycle management, ensuring that submissions are in support of company goals, of the highest quality, and delivered on-time.
- Ensures compliance with all Quality objectives for all product development teams.

- Perform internal audits, quality reviews, and gap analyses of company processes and systems to determine compliance with applicable regulatory requirements, guidance and procedures.
- Provides Metrics for Quality and Regulatory Monitoring/Management Review.
- Responsible for compliance with the company's quality system requirements through training and adherence to policies, procedures and processes.
- Provides regulatory and quality guidance to Operations and Product Development Team.
- 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 departments; develops schedules and performance requirements and ensures they are met.

NOTE: This Job Description is intended to outline general functions of relevant position and shall not be considered as comprehensive definition of specific tasks that will be required. Furthermore, specific duties of this position are subject to change as Company, Department and circumstances change. All employees are expected to perform their duties within their ability as required by the job and/or as requested by management.

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Employee Signature Date	Supervisor Signature Date
Print Name:	Print Name: