CORGENIX, INC.
POSITION DESCRIPTION

I. IDENTIFYING INFORMATION:

Job Title: Quality Assurance Associate

Department: Quality and Regulatory Affairs

Reports to: Quality Assurance Supervisor

II. GENERAL PURPOSE:

Oversees Quality Assurance activities to ensure compliance with regulatory agencies, ISO and Corgenix requirements. Performs a broad range of tasks which may include risk management, validation, maintenance, support, training, and implementation of Quality Systems, Policies, and Procedures.

III. KEY RESPONSIBILITIES:

1. Supports the implementation and maintenance of the Quality System
2. Final disposition authority for incoming materials, including packaging and labeling, used in product manufacturing. Responsible for reviewing manufacturing documentation with a presence on the manufacturing floor.
3. Oversee Purchasing Controls for critical A and B materials in accordance with the Approved Vendor list and regulatory requirements.
4. Manage the Approved Vendor List, additions and removals.
5. Review and final approval authority for device history records, new documents/new document revisions prior to distribution.
6. Assist in establishing document approval and change control procedures. Assist with document control procedures, as necessary.
7. Manage filing and database inputs of quality documents (e.g. NCR, PDN, RP, housekeeping records, Material Action Tickets, Action Impact Reviews, device history records).
8. Coordinates the Corrective and Preventive Action (CAPA) process to ensure compliance to regulatory and internal requirements and to ensure actions are completed in a timely manner. Manages the nonconformance handling system to ensure all nonconformities are identified, investigated and entered into the CAPA system, if necessary
9. Conduct and assist as needed with the Corgenix Internal Audit Program.
10. Maintain the Corgenix Training Program and assist with company awareness of the Corgenix Quality System and provide support and training on Quality issues.
11. Oversee Metrology Program – Work Order approval/closure
12. Other duties as assigned by Supervisor.

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IV. CONTACTS;

INSIDE COMPANY: Works closely with Quality Control, Document Control, Manufacturing, Marketing, Regulatory Affairs, and R&D.

OUTSIDE COMPANY: Raw material suppliers concerning quality and compliance issues. FDA and ISO regarding compliance issues.

V. JOB TITLE DIRECTLY SUPERVISED: N/A

VI. WORKING CONDITIONS

This position primarily functions in a typical office environment. Due to the interaction with Quality Control and Manufacturing, this position will occasionally function in a laboratory setting with risk of exposure to biological and chemical hazards associated with such a setting. The position requires a moderate level of mental exertion, with the individual having to respond to short deadlines and crises. The position may require in excess of forty hours per week and generate a moderate amount of stress.

VII. SPECIALIZED EQUIPMENT USED:

General office equipment including personal computer hardware, standard computer software (e.g., word processing, spread sheets, database, statistical programs), copiers, Fax machines, paper shredder, paper binding equipment, and printers.

VIII. ACCOUNTABILITY/SCOPE OF THE POSITION:

This position is accountable for the Quality Assurance activities of the company. It is a highly visible position, integral to the Company's short and long term success. This position is key to the long and short term success of the company and requires a high level of commitment to the goals set by the Quality Department and the company.

IX. MINIMUM POSITION REQUIREMENTS:

KNOWLEDGE: The position requires excellent knowledge of FDA and international regulations, directives and standards governing medical devices.

EXPERIENCE: This position requires a minimum of three (3) years' experience in Quality Assurance or Regulatory Affairs in an FDA regulated industry plus a Bachelor's Degree -or-

A minimum of (6) years' experience in Quality Assurance or Regulatory Affairs in an FDA regulated industry.

The position requires strong communication and interactive skills in cross functional participation and must demonstrate the ability to work and think independently. This person must also have the ability to investigate and resolve quality problems.

Solicits and accepts the ideas of others, as well as actively contributes to an environment conducive to open communication. This person is a highly precise worker who remains skeptical while respecting authority. Demonstrates the ability to communicate effectively both verbally and in writing, has the Knowledge and use of relevant PC software applications and skills to use them effectively and must be detail oriented.

Please send your resume including salary requirements to msailakham@corgenix.com or fax to 303-457-4519. For more information about our company, please visit our website at www.corgenix.com.