## Quality Assurance Manager
## West Chester, PA

We are seeking a dedicated and detail-oriented Quality Assurance Manager to oversee our quality assurance processes and ensure compliance with industry standards. The ideal candidate will possess a strong background in quality management systems and regulatory requirements, including ISO 13485 & 90001, FDA regulations and GMP. This role is crucial in maintaining the integrity of our manufacturing processes and ensuring that our products meet the highest quality standards.

The position may require cross shift availability based on staffing and facility support needs.

**Applicants must be authorized to work for ANY employer in the U.S. We are unable to sponsor or take over sponsorship of an employment Visa at this time.**

**Key Responsibilities/Deliverables:**

- Ensure compliance with all applicable regulatory requirements. Serves as support to and/ or primary contact/ lead for FDA, Customer, and internal audits (FDA, ISO 13485 & 90001, GMPs, Organic Regulations)
- Oversee and manage the Quality Assurance Team for the facility
- Assure quality management system activities including document control, complaints, internal audits, nonconforming material reports, CAPA, inspection activities for product through production cycle to include release authority, specification writing and deciphering and distribution to include tracking, quality records maintenance, training and Management Review are functioning at each facility, drafting and participating in validations. Prepare/ assist in preparing scorecard of continuous improvement within each facility. Author, owner, and approver for documentation to include: work instructions, SOPs, records, logs, packing instructions
- Assure the Havpak, Inc. SIP Quality Elements are applied throughout the facility
- Initiate and perform annual GMP training
- Represent and/ or support the company during medical device regulatory agency audits and inspection.
- Ensure the company has effective systems which result in compliance with medical device regulations and standards including reporting incidents to the FDA and Customers
- Provide training as to and or perform internal SIP audits creating schedule and training others as Owners and Auditors
- Maintain excellent working relationships with the FDA, other regulatory agencies, internal project team members, collaborators/partners and Customers.
- Provide release approval of materials and finished product and train others on the release approval processes
- Oversee the analytical lab and lab owner

**Education and Experience**

- Bachelor degree preferred
- Ability to multi task is a must!
- Minimum 5 Years experience with a medical device company and/ or ISO 13485
- Experience developing and maintaining a Quality system compliant with regulatory requirements

- Experience managing scheduling, evaluations and counseling of direct reports, training, interviewing and hiring
- Certification in Quality Systems as practitioner and auditor preferred
- Knowledge of FDA 21 DFR Part 820 and ISO 13485 preferred
- Computer skills – WORD, Powerpoint, Excel, SAP, Smartsheets
- Ability to work with cross functional teams
- Must be able to read, write and speak fluent English

**Working Environment**

- Prolonged periods of sitting at a desk and working on a computer.
- Must be able to lift up to 15 pounds at times.
- Frequently works in a Manufacturing/Warehouse setting

**EEO**

Havpak, Inc. is an equal opportunity employer that does not discriminate on the basis of race, national origin, gender, gender identity, sexual orientation, protected veteran status, disability, age, or other legally protected status. Our goal is to be a diverse workforce that is representative of our customers and communities. We are committed to building a team that is inclusive of a variety of backgrounds and perspectives.