Quality Document Control Specialist
Malvern, PA

We are seeking a detail-oriented and organized **Document Control Specialist** to join our Quality Assurance team. The ideal candidate will be responsible for managing, organizing, and maintaining documentation in compliance with industry standards. This role requires a strong understanding of document management systems, technical writing skills, and familiarity with FDA standards. The Document Control Specialist will play a crucial role in ensuring that all documents are accurate, up-to-date, and easily accessible.

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.

This position will require occasional overtime and weekends.

Role Description:

- The Document Control Specialist will assist the quality assurance manager/ department with various clerical tasks related to the quality assurance/ control documentation (transcribing documents, maintain control files, preparing report files, tracking training). They may be called upon to cross train in sensory, quality inspections, and other area as resources needed.

Key Responsibilities/Deliverables:

- **Specifications:**
  - Receive approved specifications from QA manager and track receipt and revision, distribute specifications to appropriate facility locations, retrieve obsolete specifications and file
  - Perform monthly specification check to assure specifications are current and available Controlled Documents
  - Receive drafted documents and transcribe documents to official control format
  - Track documents and revisions
  - Distribute controlled documents for approval signatures
  - Retrieve obsolete documents, track, and file
  - Perform monthly check of all controlled documents for file and distribution accuracy
  - Manage Two-year document review program

- **Training Matrix:**
  - Maintain to current Master Table of Contents revisions and dates
  - Update Matrix to current trainings
  - Audits training documentation throughout the facility and provides findings

- **Reporting Systems:**
  - Receive SIPs, change controls, NCRs, CARS, and Customer Complaints from QA manager and record/ file according
  - Distribute the documentation from the above systems to appropriate personnel
  - Perform monthly check on status of the above systems and report back to QA manager

- **Additional Responsibilities:**
    - Maintain retain sample (incoming and FG) organization and record/ tracking
    - Maintain calibration schedule
    - Perform Mock Recall
    - Review of incoming and production documentation
    - Help manage Validation documentation
    - Help during customer audits
    - Assists in providing quality control checks throughout the facility
    - Provides added compliance support and monitoring
    - Adds additional resource for Sensory Panelist Requirements
    - Assists QA manager with administrative support
    - Assist in training of Havpak employees
    - Read Specifications and review them to documentation
    - Must be able to help maintain FDA, Havpak and customer expectations

Knowledge, Skills and Experience Required for Success:

- Demonstrate ability to work under pressure with accuracy and efficiency
- Demonstrate ability to be part of multi-functional team.
- Ability to evaluate quality control and quality assurance statistics.
- Ability to plan workload and remain flexible if changes are required due to demands
- Ability to perform and record information accurately, prepare and organize records and reports
- Ability to deal with staff and the Customer in a positive and successful manner.
- Ability to demonstrate highly conscientious work performance
- Demonstrate working knowledge of Word and Excel and Inventory Systems
- Must be detail oriented
- Must be able to read, write and speak fluent English

Work Environment/Physical Demands:

- Must be able to stand and sit for long periods of time
- Must be able to lift 25-30 lbs.
- Must be able to handle stronger orders
- Must be willing to become sensory certified – tasting/smelling product
- Must be able to work overtime or off shifts if necessary

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.