

## **Quality Assurance and Regulatory Affairs Specialist – BRATTLEBORO, VT**

New Chapter, Inc., a manufacturer of organic vitamin and herbal supplements in Brattleboro, VT is looking for a dynamic individual to join our mission-driven, organization. We seek a Quality Assurance and Regulatory Affairs Specialist to support the Quality Assurance Department in a culture that fosters wellness and social responsibility.

### **Position purpose:**

Though some daily operational responsibilities are assigned, the primary responsibility is to manage the various projects involved with QA/QC and Regulatory Compliance. This requires a great deal of flexibility, as priorities will frequently and constantly change; time management will need to adjust accordingly.

### **Essential Duties and Responsibilities:**

- Labeling systems administrator: master file management and label proofing
- Project responsibilities as assigned and prioritized by Director QA/QC and Regulatory Compliance
- Manage State and Federal applications, licenses and regulatory documents
- Labeling: reviewing and authorizing all labeling for compliance content
- All FDA, FTC and USDA correspondence including Structure Function Claims, NDIs and NOP certification
- Creation of new Regulatory Sheets for new products and requesting of documents for new product launches
- Version control management
- Creation of new product substantiation binders
- Change Control file and database management
- GMPs – system and process validations – FDA Protocol
- Back-up International Regulatory Compliance as needed
- Prepare SOPs for distribution and finalize RDLs for use
- Review and approve website updates
- Other special project responsibilities as assigned

### **Experience and Qualifications:**

- BS Degree in Food Science, Life Sciences or similar required
- Graduate Degree in Regulatory Affairs preferred
- Minimum five years related experience
- Experience in database, spreadsheet, file management
- Strong organization skills
- Ability to navigate and problem solve in Navision software
- Intermediate Excel skills
- Efficient data entry and database management skills
- Highly detail oriented with a strong desire to work with a variety of information
- Ability to multi-task
- Strong communication skills with the ability to communicate programs and policies thoroughly
- Team player

We offer an outstanding benefit package which includes medical, dental, & 401(k). New Chapter is an equal opportunity employer. Qualified candidates, submit resume to [careers@newchapter.com](mailto:careers@newchapter.com).