Eversea Inc.

Position: Regulatory Affairs and Quality Manager
Department: Regulatory Affairs
Location: Summerville, PEI

Company Overview:

Eversea Inc. is an organic consumer products nutrition company and a world leader in research and development of nutraceutical products. The Company's PEI Research and Development facility has global expertise in the latest biological technologies that are directed to develop and commercialize sustainable animal and human health products, nutraceuticals, and biologics. The company has developed and patented the world's first Omega-3 nutraceutical product(s) that are ocean based (DHA & EPA) and organic.

Position Summary:

The key role of the Regulatory Affairs and Quality Manager is to ensure Eversea products are manufactured and distributed according to Canadian, as well as international regulations. This includes maintaining quality compliance with Good Manufacturing Practices (GMP) and associated written materials including Eversea Standard Operating Procedures (SOPs). The regulatory function requires writing, editing and managing regulatory dossiers for food, natural health products and biologics, including written responses to reviewer comments and liaising with regulatory agencies for license and product submissions. This role also requires reviewing product labels and packaging for compliance with respective international guidelines and communicating regulatory requirements internally to ensure that R&D-generated data is supportive of submissions.

Key Duties and Responsibilities:

- Draft documents in cooperation with Product Development, Production, and Quality Control Staff for submissions (Standard Operating Procedures, Operations Documentation, Regulatory Submissions)
- Design, edit and revise regulatory compliance areas of product labels, inserts and other packaging as required
- Collect and collate all written materials and data for new product submissions and formats dossiers accordingly with respect to each relevant jurisdiction
- Prepare written responses to regulatory review comments to resolve submission deficiencies
- Interfaces with R&D to ensure that generated data is supportive in form so as to be viable for as many regulatory agencies as possible
- Interpret new and existing laws, regulations and guidelines for compliance requirements to assist staff in product development, manufacture and quality control/assurance
- Participate with internal Operations and Marketing in the identification, resolution, and continued management of Regulatory Affairs compliance issues
- Keep abreast of upcoming changes in the regulatory landscape; updating R&D and Production of any impending changes
- Manage and maintain Quality Assurance (QA) dossier archive and QC master files for all registered products
- Perform equipment and process validation

3867 Greenfield Rd. Summerville, PE. C0A 1R0, Canada
Phone: (902) 838-8010 Fax: (902) 892-4426

- Spear head self-inspections, and quality agreements with manufacturers and distributors
- Assist in conducting inspections of manufacturers and distributors as necessary per GMP requirements
- Hosting inspections and third-party audit proceedings

Requirements:

- B.Sc. in Science or equivalent
- Experience in a related industry with experience in Quality Assurance, Quality Control, and/or Regulatory Affairs is considered an asset.
- Understanding of GMP environment (food, health product or biologics) and laboratory work
- Detail oriented person
- Excellent organizational skills and the ability to handle and prioritize multiple projects
- Excellent communication skills (verbal, written, listening, conveying messages)
- Solid computer skills including MS Office

Salary commensurate with experience.

Closing Date: May 14th, 2021

To Apply

If you are interested in this opportunity, please apply by submitting your resume to garth.greenham@eversea.ca

3867 Greenfield Rd. Summerville, PE. C0A 1R0, Canada
Phone: (902) 838-8010 Fax: (902) 892-4426