

US Regulatory Scientist/Project Manager Position

Position Overview:

GRAS Associates, LLC, a fully owned subsidiary of Nutrasource Pharmaceutical and Nutraceutical Services, is seeking a Regulatory Scientist/Project Manager to support the US Nutra Regulatory Sciences team. The Regulatory Scientist will provide project management, regulatory and scientific leadership and support for various food and dietary supplement projects. The responsibilities of the successful candidate include preparation of various regulatory dossiers (GRAS and NDIN), ingredient compliance reviews, product labeling reviews and maintaining and updating internal library of regulatory compliance documents and templates. Experience with preparation of dossiers for live microbial or botanical derived ingredients is preferred.

The office-based location for this position is North Bethesda, MD; however, remote working is possible for the appropriate candidate.

Primary Responsibilities:

- Project management for various US Regulatory projects and assistance with preparation of GRAS dossiers and NDI Notifications
- Interact with internal and external groups to provide US regulatory consultative support for projects
- Initiate and manage regulatory projects to ensure content complies with emerging or new requirements
- Identifies gaps in submission dossier to meet requirements
- Lead and provide guidance in the development and implementation of regulatory strategies
- Liaise with functional areas to coordinate and compile information required for regulatory documentation
- Ability to communicate and resolve any complex issues and activities related to regulatory submissions
- Interpret and make decisions relating to regulatory guidelines and policies
- Advise management on changes to regulations, standards and legal stipulations, and update SOPs and templates to reflect such changes
- Liaise with FDA and other regulatory agencies as needed
- Maintain positive and cooperative communications and collaboration with all internal and external stakeholders
- Other duties as required and as training and experience allow
- Maintain an attitude and philosophy consistent with the Company's standards



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Core Competencies:

- Proficient knowledge and experience of US regulatory requirements for food, food ingredients and dietary supplements and current regulatory issues and regulations for the U.S. food and dietary supplement sector
- Project management experience
- Excellent organizational time management and communication skills
- Excellent interpersonal and public relation skills with ability to work well in a team
- Solid problem-solving skills with an ability to identify solutions to problems under critical deadline constraints
- Ability to work independently with efficiency and accuracy and high attention to detail
- Strong technical writing skills, and ability to review and critique regulatory documents
- Computer proficiency with MS Office, with high level expertise with MS Word and Adobe Acrobat

Qualifications:

- Minimum Bachelor's degree in a scientific discipline or equivalent qualification
- Minimum 5 years specific experience in regulatory sciences, with dossier writing/submission experience preferred
- Experience with regulatory submissions for live microbials or botanical ingredients preferred

We thank all candidates for their applications, however, only those candidates selected for an interview will be contacted. Please send your application to hr@nutrasource.ca