



Director, Global Scientific & Regulatory Affairs - OmniActive Health Technologies, Inc. | Morristown NJ

Job Purpose and Scope

- Understand and apply the global regulatory requirements across geographies to ensure OmniActive's product and claims compliance.
- Be at the forefront of strategic changes in the regulations that may impact OAHT and identify approaches to address regulatory hurdles and opportunities.
- Understand how science can be leveraged as a tool to guide regulatory policy & claims substantiation

Key Accountabilities

Regulatory and Science Compliance:

- Provide regulatory guidance as per country-specific standards throughout the product lifecycle: formulation development, preclinical and clinical study design, and product and claims registration
- Co-Lead, manage and support regulatory registrations, submissions, and notifications, globally – provide technical and scientific review and quality control of regulatory submission materials
- Conduct regulatory risk assessment for existing and new products and guide appropriate mitigation plans
- Support publication strategies (preclinical, clinical and safety data) to support regulatory submissions
- Ensure published information and promotional/advertising material including claims meet country-specific regulatory requirements
- Be involved in the review of regulatory and scientific material as part of the due diligence process as part of M&A projects

Regulatory Vigilance and Advocacy:

- Monitor the rapidly changing science and regulatory landscapes to identify potential opportunities, threats and risks to the OAHT portfolio and business
- Help build and maintain credible relationships with regulatory authorities and influential trade organizations globally
- Identify and establish a nucleus of industry regulatory and scientific experts

Regulatory Processes:

- Establishing an efficient repository and archive for correspondence compliant with regulatory standards for registrations, dossier submissions, audits, and customer requests
- Create and implement processes to help team members comply with registration standards and practices
- Participate in Educational Lecture Series to disseminate information and keep the OAHT organization abreast of new science and regulations

Education & Experience

- MS/PhD
- 10+ years work experience in regulatory and scientific affairs

Skills & Competencies

- Business Acumen
- Regulatory Knowledge
- Scientific Knowledge
- Problem Solving
- Decision Making
- Customer Focus
- Budget Management
- Strong Communication Skills (Written & Verbal)

About the Company



OmniActive has a robust portfolio of scientifically validated, IP-protected, branded Specialty Actives as well as an extensive line of natural Botanical Actives for all of your formulation needs. We help nutrition brands around the globe meet the demands of the dynamic health and wellness marketplace by delivering innovative ingredients that help their products stand out.

How to Apply

Please send resume & cover letter to Anne Nunan, Human Resources at a.nunan@omniactives.com