



DIRECTOR – REGULATORY AFFAIRS

Columbia, Maryland

Department: Regulatory Affairs
Reports To: Vice President – Regulatory Affairs
FLSA Status: Exempt

Company:

Martek Biosciences Corporation (NASDAQ: MATK), a local biotech company, is a leader in the innovation and development of DHA omega-3 products that promote health and wellness through every stage of life. The company's flagship products are *life'sDHA*[™], a sustainable and vegetarian source of the omega-3 fatty acid DHA (docosahexaenoic acid) for use in foods, beverages, infant formula, and supplements; and *life'sARA*[™], an omega-6 fatty acid produced from fungus. ARA (arachidonic acid) is the primary omega-6 fatty acid in the brain and is important for proper infant brain development and physical growth.

Job Summary:

Ensure worldwide regulatory compliance for the Company's products.

- Implement the Company's worldwide regulatory strategy.
- Interact directly with regulatory agencies worldwide to gain new product approvals and ensure that marketed products are in compliance with applicable regulations.
- Monitor regulatory decisions, guidelines and enforcement activities to identify changes in the regulatory environment that might affect the Company.
- Ensure that Company-sponsored clinical studies are conducted and reported in compliance with applicable Good Clinical Practice (GCP) regulations.
- Ensure that pre-clinical studies intended for submission to regulatory agencies are conducted and reported in compliance with Good Laboratory Practices (GLP) regulations.

Essential Duties and Responsibilities:

1. Establish and maintain effective working relationships with regulatory authorities externally and company personnel internally.
2. Provide recommendations on overall regulatory strategy for the Company and implement strategy for product approvals based on pre-clinical and clinical studies and new manufacturing or testing procedures. Obtain approvals and new indications for existing products.
3. Develop proposed product claims jointly with scientific affairs, medical affairs clinical research and marketing. Aggressively pursue the broadest claims that the scientific data support by preparing and submitting claims where pre-market approval is required.
4. Effectively communicate regulatory strategy and the status of its implementation to project teams.
5. Direct preparation of documents to support regulatory applications and reporting requirements.
6. Arrange meetings with regulatory agencies and negotiate directly with representatives of those agencies.

7. Ensure collection, review and reporting of safety data, including adverse experiences to meet regulatory requirements. Oversee reporting requirements to FDA.
8. Ensure that labeling, advertising and promotion of Company's products meet regulatory requirements.
9. Keep current with regulatory matters that might affect the Company and formulate appropriate company responses to any changes or other developments affecting the regulatory environment.
10. Ensure that Company-sponsored clinical studies are initiated, conducted and summarized in compliance with ICH GCP guidelines.
11. Ensure that Company-sponsored pre-clinical studies intended for submission to regulatory agencies are conducted and summarized in compliance with GLP regulations.
12. Maintain a central file of all pre-clinical and clinical study documents conducive to inspection by regulatory auditors.

Supervisory Responsibilities:

Manage and mentor Regulatory Affairs Manager and Associate

Qualifications:

1. PhD desirable. Proactive, flexible individual with 8+ years management experience interacting with government agencies regulating nutritional supplement, food, medical foods, biological or pharmaceutical products.
2. Demonstrated success in gaining product approvals and working within a dynamic regulatory environment required.
3. Ability to recognize a changing regulatory environment and act to influence regulatory policy.
4. Knowledge of the structure of regulatory framework for the major worldwide market areas, especially US, Europe and Asia is necessary.
5. Knowledge of applicable regulations for infant formula, nutritional supplement, food and pharmaceutical applications for major market areas required.
6. Detailed knowledge of GCP, GLP and current GMP regulations.
7. Strong management and organizational skills.
8. Excellent oral and written communication skills required.
9. Demonstrated ability and willingness to work within a project team environment.

Requirements:

Physical Demands:

N (N/A) A (1 – 25%) B (26 – 50%) C (51 – 75%) D (76 – 100%)

Sitting	<u>C</u> %	Standing	<u>A</u> %
Walking	<u>A</u> %	Driving	<u>N</u> %
Bending/Stooping	<u>N</u> %	Climbing	<u>N</u> %
Reach above shoulder	<u>N</u> %	Kneeling	<u>N</u> %
Pushing/Pulling	<u>N</u> %	Crawling/Crouching	<u>N</u> %
Lifting	<u>10</u> lbs		

Computer work

_____ N/A _____ Minimal X Moderate _____ Significant

Temperature extremes

_____ N/A X Minimal _____ Moderate _____ Significant

Noise

N/A Minimal Moderate Significant

Travel:

Domestic % International %

Please submit your resume and/or application (www.martek.com) to Human Resources at jobs@martek.com or fax to 410-772-5811. Recruiters welcome.

Martek Biosciences Corporation is an Equal Opportunity Employer.
M/F/V/D