Director Regulatory Compliance
JDS Therapeutics, LLC
Purchase, NY

Company Description:
JDS Therapeutics discovers, develops and commercializes natural, bioactive substances that improve human health and wellness. Our innovative research has resulted in more than 100 issued and pending patents on natural compounds. What makes JDS Therapeutics unique is that we approach the development and commercialization of these compounds with the same scientific rigor and investigative approach as traditional pharmaceutical products.

JDS Therapeutics has two business units through which we market and distribute the products we develop: JDS Women’s Health and Nutrition 21. The management at JDS Therapeutics significantly grew Nutrition 21’s legacy ingredient business and leveraged it as a platform for the creation of JDS Therapeutics. Through its second commercial arm, JDS Women’s Health, JDS Therapeutics has been developing its intellectual property into a number of exciting products, including multiple new drugs and healthcare supplements.

Job Description:
The Director Regulatory Compliance will proactively focus on regulatory compliance of the Company’s finished products and raw materials sold in the US and Internationally. The Director Regulatory Compliance will have a strong working knowledge of 21 CFR Part 110, 21 CFR Part 111, 21 CFR Part 117 and the Food Safety Modernization Act (FSMA) and will identify regulatory gaps and work to close them. He/she will review the company policies and procedures to ensure they comply with federal, state and local regulatory guidelines. The Director Regulatory Compliance will also work closely with Quality, Legal, R&D, Sales, and Marketing departments, and will report to the Corporate General Counsel.

Responsibilities:
- Ensure that domestic and/or international dietary and food regulations are met.
- Lead the regulatory function to provide support to enable Sales and Marketing to continue to sell current in-market products or launch new products.
- Help establish and maintain procedures and processes to ensure regulatory compliance.
- Support Company with routine and non-routine contact with contract customers concerning Regulatory matters.
- Prepare regulatory-mandated label copy for dietary supplements and/or health foods, to meet various country-specific regulations.
- Proof-read and approve label artwork based on an understanding and interpretation of product formulas, labeling, claims and other applicable regulations, contract provisions, account preferences and Corporate policies.
- Monitor formula changes and label revisions to assure compliance with domestic or foreign regulatory requirements.
• Review formulas, bills of materials and specifications for regulatory compliance.
• Apply knowledge of US FDA regulatory requirements, cGMP’s, ICH guidelines, and Company policies to problems and provide appropriate resolution.
• Keep abreast of regulatory changes in the U.S. or foreign countries and ensures that key personnel are kept up-to-date on such changes.
• Perform other related duties as assigned.

Qualifications:
• Bachelor’s degree or higher, preferably in life sciences or related area.
• Minimum 10 years of experience in Regulatory within the dietary supplement and/or food industry.
• Minimum of 5 years management and decision making experience.

Required Skills/Abilities:
• Working knowledge of Dietary Supplement Health and Education Act (DSHEA).
• Working knowledge of 21 CFR Parts 110, 111 and 117, and FSMA.
• Knowledge of current FDA and FTC guidance documents and enforcement policies within the food and dietary supplement industries.
• Experience in working with finished products and raw materials.
• Ability to understand and interpret clinical trial reports, medical journal articles and other medical/scientific materials that support product claims.
• Ability to read and interpret regulations, guidance documents, technical manuals, handbooks, formulations, and product specifications.
• Demonstrated ability to be proactive, independent, highly motivated, and effective in managing multiple projects.
• Excellent communication skills with the ability to clearly communicate orally and in writing.
• Excellent planning, prioritizing and organizational skills.
• Highly proficient with corporate software tools - Microsoft office suite including Word, Excel, PowerPoint.

JDS Therapeutics Benefits
As a member of the JDS Therapeutics team, employees enjoy competitive salaries and an exceptional benefits package featuring medical, dental, vision, 401K, life insurance, long term disability coverage.

Equal Employment Opportunity
JDS Therapeutics is committed to equal opportunity in the terms and conditions of employment for all employees and job applicants without regard to race, color, religion, sex, sexual orientation, age, gender identity or gender expression, national origin, disability or veteran status.