Director/Manager – Regulatory Affairs

Klus Pharma Inc.

Location: Princeton Area, NJ

If Interested, please send resume to HR@kluspharma.com

The Regulatory Affairs Director/Manager is responsible for directing and managing a team of regulatory professionals for the on-time filing of high-quality regulatory ANDA submissions and for post-approval maintenance of regulatory dossiers. S/he mentors and provides regulatory guidance to team members. The director/manager interacts with all levels in the organization. S/he participates in discussions with management and provides strategic regulatory guidance. The director/manager interfaces with regulatory agencies, primarily the FDA, as it relates to submissions and other relevant topics.

Essential Responsibilities:
The director/Manager is responsible for effectively

·Managing and prioritizing the team's workload in accordance with departmental goals

- Ensure that CMC teams work effectively and productively and have proper coordination with assigned labeling and publishing member

·Motivating staff and maintaining the team's focus on departmental objectives

- Sharing best practices for planning, organization and time management

· Overseeing the preparation and filing of high-quality ANDA submissions to regulatory authorities

· Ensuring that all applications are filed in accordance with predetermined timelines

· Providing expert regulatory strategy/guidance to staff and inter-disciplinary project teams

- Applying expert knowledge of industry conditions and opportunities for competitive advantage to make business recommendations
- Primary point of contact for FDA on Klus Pharma ANDAs
- Interact and negotiate with FDA regarding strategy and resolution of complex deficiency issues

- Gathering deep insight into the industry (pharma and/or device) by actively participating in professional organizations
- Developing quality standards for RA
- Continually adapting and innovating processes to ensure best practices
- Ensuring that department management is aware of team activities and progress
- Developing staff and conducting mid-year and annual reviews of staff
- Projecting professionalism and a courteous, cheerful and cooperative demeanor
- Other duties as assigned

Requirements:

- BS degree or higher in a scientific discipline, advanced degree is desirable
- At least 10+ years industry experience and (5) years related managerial experience in the pharmaceutical industry with extensive knowledge of regulatory affairs
- Strong background and knowledge on drug development process and in-depth knowledge of FDA and EU regulatory requirements
- Previous experience in leading submission teams for FDA ANDA injectable applications
- Experience with ANDA parenteral drug product development or manufacture is desirable
- Strong communication, interpersonal, and negotiation skills; Strong knowledge of cGMP