Job Title: Associate Director of Regulatory Affairs

Location: Covington, GA

Job Summary:

As Associate Director, Regulatory Affairs, you will be responsible for managing a team that develops and executes the strategy and timelines for submission of various regulatory licensing activities for new and currently marketed products.

Job Responsibilities:

- Serves as primary regulatory body liaison including managing audits, responses, and new submissions, and RA leadership team representative.
- Responsible for the global regulatory strategy for UCC products
- Leads the RA function on assigned complex, cross-functional project teams; establishes appropriate communication within RA and other functions at project and upper management levels.
- Provides regulatory strategy, risk evaluation and mitigation recommendations to project teams; develops and documents sound regulatory decisions and justifications for complex and high-risk facility, product, and process changes.
- Ensures project team and business objectives and deliverables are aligned with regulatory strategy and submission timelines.
- Orchestrates the format and information in the development and execution of regulatory submissions.
- Ensures accuracy of Clinical documents in compliance with Clinical Trial regulations for submission to FDA for execution of Clinical Studies.
- Provides guidance and coaching to maintain effective collaboration as a Global RA team and to synchronize domestic and international submissions.
- Proposes gap analysis of proposed and implemented regulatory guidance documents and regulations to propose solutions.
- Provides direct supervision of individuals.
- Provides guidance on development and review of labeling and promotional material for compliance with regulations; works closely with Legal and clinical team to ensure compliance with regulatory requirements.

- Presents regulatory project updates, risks and regulation or guidance changes to Corporate Quality and Regulatory Affairs. International Regulatory Affairs and Senior Leadership.

Job requirements:

- Minimum BA or BS required, preferably in a scientific or health related discipline.
- Minimum 10 years' experience in Regulatory Affairs, and/or a combination of Regulatory Affairs and Quality Assurance within the Medical Device industry.
- Knowledge of healthcare-related regulatory bodies such as FDA, Notified Bodies, Health Canada, TGA, etc.
- Understanding of related disciplines in an FDA regulated organization.