Manager, Regulatory Affairs

RoosterBio Company Overview

RoosterBio designs, manufactures and distributes advanced cells, media, and reagents aimed at radically simplifying and accelerating development and commercialization of products using living cellular technology. We proclaim the dawn of a new day is here in the fields of cell technologies and regenerative medicine, including bio-fabrication and tissue engineering. RoosterBio is a revenue stage company on a rapid growth trajectory. Our team is passionate about delivering the best human mesenchymal stem/stromal cell products and services to our customers. We are uncompromising on quality, innovation and product performance. RoosterBio believes in hiring and developing the best talent and has built an award-winning culture with positive, solution-focused, high-performing people. The pace is fast, the work is stimulating, and the best is expected out of each team member. If you have a genuine passion for helping invent the future of cell-based technologies, we invite you to apply!

The Role

We are looking for a highly motivated regulatory affairs professional to manage the regulatory activities for RoosterBio's ancillary and cellular starting materials for further manufacture of regenerative medicine products in domestic and international markets. The incumbent will play a key role in understanding the global regulatory landscape in the rapidly expanding cell and gene therapy industry to ensure RoosterBio's current and expanding product line can be seamlessly introduced into our customers' regulatory filings.

Essential Job Duties

- Prepare and coordinate high quality regulatory submissions, reports, and correspondences for cGMP media and mesenchymal stem/stromal cell banks from GTP-compliant donor/tissue sources. This includes writing significant CMC sections for Master Files with input from internal and external teams.
- Help define regional and country-specific regulatory requirements in major global markets and develop strategies to gain market entry for multiple ancillary and starting materials.
- Lead efforts in generating dossiers for individual products including identifying required content to ensure compliance in meeting regulatory guidelines and requirements for cellular products and bioprocessing media in various jurisdictions.
- Manage the current US FDA Master Files to ensure annual updates are accurate and complete. This includes assessing change controls for regulatory impact.
- Monitor emerging trends regarding industry regulations and maintain awareness of evolving regulatory requirements or developments that pertain to RoosterBio products. Communicate and provide guidance to the leadership team on any regulatory changes to assure continued compliance.
- Participate in new product development, tech transfer, and launch programs to assess regulatory compliance and communicate any risk to the cross functional team to develop appropriate mitigation strategies.
- Conduct proactive gap analyses and regulatory risk assessments and development and recommend solution focused mitigation strategies to ensure that all the manufacturing and quality programs relevant to the chemistry, manufacturing and controls of RoosterBio products are appropriately structured to meet global regulatory requirements.
- Identify and respond appropriately to regulatory issues by analyzing the challenge and providing adequate and innovative solutions.
- Develop and implement departmental operating procedures such as internal guidelines for global document preparation and submissions.
- Work closely with Quality Assurance to assist hosting audits, establish Quality Agreements, assist with any compliant investigations, and other duties as assigned.

Desired Skills/Qualifications:

- Degree in Scientific Discipline (Masters or higher preferred) with a minimum of 5 years of CMC regulatory experience within the biotechnology industry, or equivalent.
- Experience in a regulated environment leading or supporting CMC regulatory submission content for a biologic; for a cell therapy a plus.
- Possess knowledge on current regulations, regulatory processes and requirements in all major global regions for biologics; experience with cellular products and bioprocessing media preferred.
- Ability to apply knowledge of FDA, EMA, JP, and ICH guidelines both strategically and operationally to develop global CMC regulatory strategies for market entry.
- Experience with compiling information and generating individual product dossiers for worldwide use.
- Possess confidence and professional demeanor to initiate and conduct meetings/consultations with various regulatory agencies.
- Excellent organizational and communication skills.
- Able to manage timelines with a sense of urgency and be flexible enough to adapt to changing priorities while maintaining a positive and collaborative attitude.

Interested individuals should apply online at: http://tinyurl.com/RoosterBio-ICP
Please visit our website at www.RoosterBio.com.