Director/Associate Director, Quality Assurance (QA) & CMC Regulatory

The Company

RoosterBio accelerates human mesenchymal stem/stromal cell (hMSC) and exosome/extracellular vesicle (EV) product and process development to fuel the rapid implementation of scalable advanced therapies. Our high-quality hMSCs, bioprocess media, genetic engineering tools, and exosome production solutions are paired with expert bioprocessing knowledge to progress therapeutic developers from concept to first-in-human testing and commercial manufacturing.

Our employees are driven by high impact work and are passionate about ensuring our client's success and creating a world where safe and effective advanced therapies are rapidly developed and widely available on a global scale.

We do not compromise on quality, innovation, or product performance. We believe in hiring and developing the best talent available within the industry. The pace is fast, the work is stimulating, and the best is expected out of each team member. It is our belief that an appreciation for a small company environment where a collaborative, solution-focused and high performing culture is of utmost importance is essential to attain personal fulfillment and success at the “Roost”.

The Role

We are seeking a highly motivated, dedicated, and results driven Quality professional to join the team to fill a new role focused on assuring the quality, safety, and compliance of RoosterBio’s ancillary and cellular starting materials for the development and further manufacture of regenerative medicine products in domestic and international markets. This hands-on Director/Associate Director, reporting to the Vice President of Quality and Regulatory, will direct an amazing Quality team to continued success in meeting strategic objectives. The ideal candidate will be highly experienced in cGMP compliance, maintaining an inspection ready quality management system and laboratory, and interfacing across the company as well as with external customers, collaborators, and vendors. Most importantly, the quality minded incumbent should be ambitious, willing to assume increasing responsibilities, and adapt to RoosterBio’s evolving structure and growth.

Essential Job Duties

- Provide strategic direction and leadership to a top-performing Quality Assurance team to foster a culture of continuous learning and development.
- Responsible for the Quality Management System, lot release functions, and operational management of all QA activities to assure the overall quality of RoosterBio products.
- Build external relationships with and oversee management of contract manufacturing organizations.
- Ensure compliance with relevant regulations and guidelines, including FDA, EMA, and other international regulatory authorities and requirements.
- Identify and assess quality risks associated with the business and develop risk mitigation strategies and ensure their effective implementation.

- Contribute to department goals by driving implementation of Quality objectives and delivering key results.
- Support/lead initiatives that accomplish continuous improvement and cost effectiveness and enhance efficiencies and compliance of processes and procedures.
- Hands on execution of Quality tasks to support Quality Operations to include
  - Monitoring the effectiveness of quality systems and processes.
  - Preparing for and hosting customer audits including providing any responses.
  - Providing exceptional customer service to internal and external clients, responding to customer inquiries and requests.
  - Oversee supplier/vendor qualification program including leading critical contract vendor audits as necessary.
  - Review and approve change controls, deviations, corrective actions, OOSs, customer complaints, and other quality system documentation.
  - Oversee internal audits to assess compliance with quality standards. Lead the internal audit program to monitor RoosterBio's state of compliance.
  - Conduct or facilitate investigations to address any customer complaints.
  - Participate in evaluation of supplier changes and risk evaluation activities.
  - Monitor, trend, and report metrics on aspects of the Quality Systems for Management Review meetings.
  - Author quality documentation as necessary.
- Support the generation/compilation of CMC Regulatory content of Master Files for clinical-grade media and cell banks.

Skills/Qualifications:

- Bachelor's or higher degree in related field. Minimum of 7+ years of Quality experience in a cGMP biologics environment.
- Strong leadership and people management skills, with the ability to inspire and continuously develop a high-performing team.
- Proven track record in maintaining the highest standards of safety, quality, and operational excellence.
- Excellent communication and interpersonal skills, with the ability to collaborate effectively across functions and levels of the organization.
- Able to make decisions in ambiguity while maintaining quality and safety.
- Ability to critically evaluate and develop solutions for problems of increasing scope and complexity.
- Able to manage multiple priorities and aggressive timelines with a sense of urgency yet be flexible enough to adapt to changing priorities while maintaining a positive and collaborative attitude.

Interested individuals should email a pdf resume and cover letter directly to Kathy@RoosterBio.com.