

Seeking Exceptional Manufacturing Sr. Associate/Manager

RoosterBio Company Overview

RoosterBio designs, manufactures and distributes advanced stem cell research products aimed at accelerating the pace of development and commercialization of products incorporating living cellular technology. We believe that the dawn of a new day is upon us in the fields of biofabrication, tissue engineering, and stem cell technologies. RoosterBio is a revenue stage company on a high growth trajectory. Our employees are driven by high impact work and are passionate about delivering the best stem cell products possible to our customers.

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 ultimate performance is expected out of each team member. Working at RoosterBio is not for everyone. It is essential to have genuine passion and commitment for the commercial translation of stem cell and tissue engineered products, as well as an appreciation of a small company environment. It is our belief that these characteristics are necessary to attain personal fulfillment and success at RoosterBio. The development of a positive, collaborative, solution-focused and high performing culture is of the utmost importance to the RoosterBio team.

The Role

We are looking for friendly, well organized, highly motivated and driven individual to join the Operations team at RoosterBio and fill a role focused on building and optimizing our manufacturing operations and enhancing our culture. This position is critical to the core product lines and will advance the RoosterBio business with responsibilities in the scheduling and producing stem cell and media products, streamlining manufacturing processes and operations, technology transfers, and helping to establish efficient and robust quality systems. All of these accountabilities are central to our customers having a good experience with our Company and our products. Ideally, we are looking for someone with leadership qualities that can take on management responsibilities as RoosterBio grows.

Job Duties

- Leading the team in the manufacturing through distribution of high volume, high quality stem cells , cell culture media, and reagents.
- Ownership around planning, organizing, directing and continuously improving all activities related to the manufacturing, release, and distribution of RoosterBio cell and media products. Routine manipulation of 10-layer cell factories is part of the job.
- Operates single-use mixing, filtration, and fill/finish systems for media and reagent preparations and final fill.
- Responsible for diligent record keeping of batch records and production documents.
- Represents RoosterBio in interactions with the local community, customers, suppliers and business partners in a professional manner.
- Provides support with customer requirements, communications and resolution of issues
- Ensures effective management, including efficiency and cost control of operations for current and future Good Manufacturing Practice (cGMP) and other applicable regulations regarding for manufacturing, facility operations, raw material procurement, storage and distribution.

- Develops reporting metrics to measure the efficiency and quality of cell and media manufacturing operations.
- Assist in internal and external technology transfers.
- Drafts, revises and updates Batch-records and SOPs with support from management and/or contractors
- Assists investigation, reporting, monitoring progress and completion of deviations and errors that trigger non-conformance reports and subsequent CAPAs to eliminate root causes completed on time as quality systems are implemented.
- Adhere to lab safety and prepares the lab for audits and visits.
- Full time position with flexibility.

Skills/Qualifications:

- Team player that projects a positive, proactive, collaborative, and helpful attitude that can be a role model as the company grows.
- B.S./M.S. in Biology or Biomedical / Biochemical Engineering related discipline with 3-8 years of relevant industry experience.
- Knowledge of aseptic technique and experience in working with biological material using Biosafety cabinets.
- Experience in Biotechnology, Medical Devices or Cell Biology, and ideally Cell or Gene Therapy, with direct experience in GMP cell culture operations.
- Strong understanding and philosophical grounding in Good Manufacturing Practices (cGMP).
- Experience with Process Engineering and LSS/Operational Excellence concepts and implementation of best practices is a plus.
- Background in supervising lab operations, with exposure to Project Management practices.
- Action oriented, results driven, and able to accomplish project objectives while always striving to exceed expectations.
- Adapts to changes, demands, schedules, and priorities while maintaining a positive attitude and solution-focused mindset.
- Expert equipment knowledge to perform troubleshooting and root cause analysis for single-use mixing and fill/finish systems.
- Accepts personal responsibility for producing results (individually and as a team).
- Direct experience seeding, media exchanging and harvesting 10-layer culture vessels, and capable of passing an Aseptic Process Validation of 10-layer vessels without further training.
- Exhibits a high level of professionalism while representing RoosterBio.

Interested individuals should apply online at: <https://tinyurl.com/RoosterBio-SMA>

Please visit our website at www.RoosterBio.com.