



Engineering Manager, Manufacturing Science and Technology (MSAT)

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 friendly, well organized, highly motivated and driven individual to join the Operations team at RoosterBio and fill a newly created hands-on Engineering Manager role who will also have the opportunity to build an MSAT team and enhance our culture. This position is critical to the core product lines and will advance the RoosterBio business with responsibilities focused on internal and external technology transfer, process scale-up & engineering runs, trouble shooting, and continued support and improvement of manufacturing and related processes. 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.

Primary Responsibilities

- Lead and execute technology transfer activities to internal and external manufacturing sites and serve as technical hands-on expert in supporting all aspects of cellular and media products manufacturing, including fill-finish, storage, testing, and shipping of final products.
- Generate comprehensive process engineering and product knowledge and translate to process scale-up runs and engineering runs that leads to successful final production at scale.
- Responsible for evaluating process requirements, perform gap analysis, generate all technology transfer related documents such as process description, bill of material, technology transfer protocols, batch records, specifications for equipment, raw material and final product, as well as campaign summary reports.
- Lead the design through installation and commissioning of processing equipment/systems, training, and validation activities.
- Responsible for detailed data analysis and root cause analysis to identify solutions to complex problems and out of specification investigations.
- Perform fit-to-plant projections and plan for new processes and implement processes in multiple manufacturing facilities.
- Perform raw material and reagent risk assessment and develop risk mitigation plans. Support supplier selection processes.
- Champions and implements change controls, leads selection of new equipment and materials, and manages their implementation at manufacturing facilities to improve existing and new processes.
- Engages with program managers and process scientists to ensure projects are planned and executed appropriately in order to deliver and meet the needs of our customers and the business. Provides input to



technical development early in the process to ensure facility/operational considerations are factored into process decisions.

- Drive continuous improvement through process monitoring and statistical modeling.
- Plan and execute corrective actions to reduce process variability, improve product quality, or streamline production processes.
- Design and execute experiments as part of process scale-up, trouble shooting and OOS investigations, as needed.
- Adhere to lab safety and prepares the lab for audits and visits.

Desired Skills/Qualifications:

- Action oriented, results driven, and able to accomplish project objectives while always striving to exceed expectations.
- 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 Chemical Engineering, Biomedical Engineering or in related life sciences with at least 5 years of relevant industry experience in biologics development, process engineering, manufacturing, MSAT or operations.
- Strong analytical, problem-solving, and critical thinking skills to identify risks and prepare balanced decisions
- Hands-on experience with cell culture from bench to manufacturing scale including cell bank preparation, aseptic final product filling, labeling, liquid media or reagent manufacturing, and interpretation of routine data from manufacturing operations.
- Experience with process development and commercial scale manufacturing support for upstream and downstream cell therapy processes such as stem cell culture, bio-reactor operations, continuous centrifugation, and automated filling, is a plus.
- Knowledge and familiarity with cGMP requirements, aseptic technique, process design, scale-up/-down models, CMC tech- transfer, process control strategies, testing methods, validation, regulatory filings, and continuous process verification as applied to biologics manufacturing
- Experience with Process Engineering and LSS/Operational Excellence concepts and implementation of best practices is a plus.
- Adapts to changes, demands, schedules, and priorities while maintaining a positive attitude and solution-focused mindset.
- The ability to work in a matrix-based organization relative to changing priorities and urgency. Highly motivated with the ability to work independently as well as on cross-functional and cross-site team
- Accepts personal responsibility for producing results (individually and as a team).
- Exhibits a high level of professionalism while representing RoosterBio.

Growth Path:

Increased responsibilities as RoosterBio and its partnerships continue to grow. Further title changes and oversights to be determined. Performance goals rewarded with total compensation plan, including stock options, benefits and base salary/bonus considerations.

Interested individuals should apply online at: <http://tinyurl.com/RoosterBio-ICP>

Please visit our website at www.RoosterBio.com.