

## **RoosterBio Inc.**

### **Senior Operations Associate**

#### **The Company**

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 the best is expected out of each team member. The ideal candidate has a genuine passion and commitment for the commercial translation of stem cell and tissue engineered products. The development of a positive, solution focused and high performing culture is of the utmost importance to the RoosterBio team.

#### **The Role**

We are looking for a friendly, well organized, highly motivated and driven individual to join the team at RoosterBio and fill a role focused on building and optimizing our quality control operations as well as enhancing our culture. The incumbent will play a key role in ensuring that RoosterBio products live up to the label statement "Made with Care in Frederick, MD". This position is critical to the RoosterBio business with responsibilities in both manufacturing and quality control/quality assurance. All of which are central to our customers having a good experience with our products. Ideally, we are looking for team-oriented person who could potentially can take on increasing responsibilities as RoosterBio grows rapidly over the next 1-3 years.

#### **Essential Job Duties**

- Manage and execute basic laboratory activities including organizing materials, equipment monitoring, equipment maintenance, etc.
- Manage key relationships which include external QC contractors, suppliers, and customers.
- Manage lot release testing from sample receipt to Certificate of Analysis generation.
- Coordinate testing schedules of multiple samples.
- Perform internal QC testing procedures.
- Manage sample distribution to external QC testing labs.
- Collaborate with manufacturing and process development teams to provide customer support.
- Draft, review and update Standard Operating Procedures as needed.

## **Secondary Job Duties**

- Perform root-cause analysis for all non-conformance reports and deviations. Develop and implement corrective and preventative actions (CAPAs).
- Assist with the design and execution of Quality Systems for current and future Good Manufacturing Practices (cGMP) and other applicable regulations as required.
- Assist during manufacturing of routine cell culture products and aseptic fill procedures.
- Perform other tasks as assigned by management.

## **Desired Skills/Qualifications:**

- Projects a positive, proactive, collaborative, and helpful attitude.
- Action oriented, results driven, and able to accomplish project objectives and meet or exceed expectations.
- Experience in Biotechnology, Medical Devices and Cell Biology within GMP operations.
- B.S./M.S. with 1-3 years of relevant industry experience or A.A. with 4 – 6 years of relevant industry experience.
- Background in lab operations in the biotech/pharma industry.
- Experience in mammalian cell culture is preferred.
- Experience in drafting and revising SOPs.
- Experience with Process Improvement Activities (Lean/5S/Six Sigma, etc.).
- Adapts to changes, demands, schedules, and priorities while maintaining a positive attitude.
- Accepts personal responsibility for producing results (individually and as a team).
- Exhibits a high level of professionalism at the workplace.

Interested individuals should email a resume and cover letter to [Jon@RoosterBio.com](mailto:Jon@RoosterBio.com)

Please visit our website at [www.RoosterBio.com](http://www.RoosterBio.com)