Aseptic Manufacturing Associate

As part of the Emerging Technologies operational team this is a unique opportunity for an experienced and capable Aseptic manufacturing associate to be involved with the new manufacturing activities that encompass cell therapy at the Lonza site in Portsmouth, NH. The preferred candidate will have the following background

- Must have experience and knowledge of aseptic production processes and be a source of technical expertise. 3+ years of experience in Aseptic Fill/Finish required.
- High School Diploma is required. Certification, Associates or Bachelor's Degree in science related discipline is preferred.
- Experience with independently writing and executing SOPs and associated batch record documentation.
- Strong knowledge and adherence to cGMP compliant processing (At least 4 years' experience)
- Demonstrated support to change control process, work order generation, deviation investigation and management
- Proven logic and decision making abilities. Including real-time decision making on process events on the floor based on knowledge of defined SOPs & policies.
- Able to provide manufacturing insight into the review of more complex decisions with supervisor and support departments, plus provide input to management on scheduling or process issues based technical, process & equipment experience.
- Able to multi-task on equipment preparation and operations to ensure area stays on schedule
- Where required work unsupervised. For example perform shift exchanges independently
- Offers suggestions for improvement, implements where appropriate and is keen to develop self with respect to technical knowledge of operations and technologies
- Ability to manage multiple priorities and coordinate between departments for multiple parallel activities.
- Able to troubleshoot equipment; non-routine as well as routine troubleshooting
- Ability to communicate manufacturing operations perspective effectively to management, support department and customers.

The Aseptic Manufacturing Associate will initailly focus on supporting the equipment & operational readiness of the cell therapy project, with the intent of assuring that Manufacturing & the customer is provided with a facility that matches their requirements of quality, operability & consistency. Through the course of the project (construction, commissioning and validatation) responsibilities may also include but will not be limited to;

- Review the design of the facility & equipment and provide support to FATs, SATs & validation
- Supporting training with repsect to Cell Therapy operations. (particular emphasis on aseptic filling)
- Provide guidance and trouble shooting input during the commissioning, validation & start-up effort.
- Support the generation of SOP's and batch records for the Cell Therapy project. (particular emphasis on aseptic filling)
- Support the ordering and set-up for new small equipment required to run the area, including ensuring proper documentation is in place
- Support activities associated with setting the area up for GMP operation, and that the transition from project to GMP operation is planned for and transitioned smoothly. This will include placing systems and procedures from current operations in place prior to start up.
- During the project phase this position will have a schedule of Monday to Friday 8:00am to 4:30pm.
- Post project completion this role will transition into a traditional manufacturing schedule of 12 hour rotating shifts from 7am to 7pm (48 hours / 36 hours). The successful candidate will play a key role in these operations.

Quality should be the responsibility of all persons involved in Manufacturing. Adherence to cGMPs is required at all times during the manufacture of APIs. All personnel are responsible for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions (e.g. quality related complaints, recalls, regulatory actions, etc).

All personnel should practice good sanitation and health habits.