Manufacturing Specialist

Summary

The Manufacturing Specialist will be responsible for developing and supporting manufacturing operations with any number of upstream or downstream processes, co-developing manufacturing processes, executing Standard Operating Procedures (SOPs) for manufacturing operations, conducting equipment and process validation of manufacturing processes, performing manufacturing activities under cGMPs and complete project assignments as required to support all of these.

Essential Duties & Responsibilities

- Performs production planning, scheduling and manufacturing of components and materials to maintain adherence to production schedules.
- Follows established manufacturing procedures (computerized, verbal, and manual) as appropriate
- Follow procedures for ordering and receiving reagents and consumables.
- Create manufacturing procedures and forms. Train staff to new procedures and mentor new staff on procedures.
- Assist and lead continuous improvement projects, manufacturing scale up and validation efforts.
- Identifies problems that may adversely affect the manufacturing process and reagents; and appropriately reports and resolves them following established procedures.
- Lead and manage the completion of change records, nonconformances, investigations and CAPA's.
- Experience with laboratory equipment including but not limited to use, maintenance and troubleshooting.
- Experience with equipment operation and/or the flexibility and desire to learn operation of new equipment.
- Self-motivated with an enthusiastic, positive attitude, and excellent multi-tasking skills.
- The ability to work effectively both independently and in a fast-paced, client-oriented, team environment.
- Assist in general laboratory maintenance including environmental monitoring, inventory management, and routine cleaning
- Follow guidelines necessary for regulatory compliance
- Work closely with supervisors and other employees
- Contribute ideas and feedback to improve laboratory processes
- A flexible schedule to perform off-shift work if required

Education & Experience

- Bachelor's degree in life sciences or related field, preferably molecular biology
- Experience working in a clinical laboratory, research laboratory and/or biotech manufacturing environment a plus.
- Ability to follow written procedures with minimal direction
- Strong documentation skills and attention to detail necessary in a GMP environment
- Ability to understand and independently apply GMPs to everyday work with regard to documentation and instrument use
- Familiarity with the concepts of quality control (QC) and quality assurance (QA)
- Familiarity with current Good Manufacturing Practices (cGMPs) and application to the manufacture of biotech material is a plus.
- Physical ability to lift items overhead and stand for a significant portion of the workday is required
- Excellent communication and organizational skills
- Strong computer skills

Compensation

TAI Diagnostics provides competitive compensation and a comprehensive benefits package, with medical, dental, and vision coverage along with life and short-term and long-term disability. We also provide a retirement savings plan that combines 401(K) with a company match. Paid holidays and vacation round out the package. TAI Diagnostics is an Equal Opportunity employer.