



Position / Job Title: Manufacturing Associate II
Job Type: Full-time, Non-exempt
Job Hours: 1st shift (with flexibility to work other shifts as business needs dictate)
Reports to: Manufacturing Supervisor

Summary

The purpose of this position is to support the manufacture of biotherapeutic molecules under cGMP for both clinical and commercial products as well as support non-GMP manufacturing.

Essential Functions

Responsibilities include commissioning equipment and executing manufacturing procedures that involve bioreactor operation, and downstream purification for biotherapeutic molecules from both mammalian and microbial sources. Responsibilities of these positions also include the execution of Validation IQs and OQs, preparation and review of technical reports, writing and reviewing GMP documentation, executing GMP manufacturing operations and, as required, supporting Process Development and Technology Development.

Knowledge, skills and abilities

Qualified individuals will be skilled in techniques in one or more relevant areas of biotherapeutic manufacturing (Cell culture, microbial fermentation, bioreactor operation, techniques for filtration and chromatographic separation), have relevant experience in manufacturing under cGMP and developing processes for cGMP manufacturing, and possess a sound knowledge of cGMP requirements. Strict attention to detail and safety are absolutely required for this position. Good written and verbal communication skills as well as process development experience (technology transfer) are not required, however recommended. A thorough working knowledge of aseptic technique is also a plus.

Working conditions

This position is technically oriented. The qualified individual will be required to work in a controlled clean room environment as well as in a development lab as required. As a 24-hour manufacturing organization off-shift work and/or support may be required to fulfill operational commitments.

Minimum qualifications

Associates will be responsible for the manufacturing of clinical and commercial products: operate production equipment such as bioreactors, centrifuges, filtration devices, and chromatography equipment; weigh and mix raw materials; assemble and clean process equipment and monitor processes. In addition, associates will maintain the records and clean room environments to comply with regulatory requirements while adhering to cGMP. Individuals in this position will be responsible for microbial fermentation and primary recovery as well as downstream operations and the execution of validation protocols.

Success factors

While the responsibilities of this position are mainly in Contract Manufacturing Operations, individuals will be able to contribute to development projects as available. Interpersonal, communication and organizational skills are prerequisite to working in an interdisciplinary team environment. The ideal individual must have a strong personal commitment to incorporate cGMP / Quality in all aspects of job performance.

Required Skills

This position requires a minimum of a high school diploma with a minimum of 2 to 4 years of relevant manufacturing experience. While candidates may have a Bachelors degree in Biology or related science, this is not required.