
PRINCIPLE ENGINEER, MANUFACTURING

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The Life Sciences Talent Bank Company

This position is responsible for implementing the process validation program for the manufacture of both new and existing biologicals at a public biopharmaceutical company in **Central New Jersey**. Responsibilities include planning, writing and managing the execution of process validation protocols, such as consistency and product comparability protocols. The authoring of manufacturing and validation sections of regulatory filings will be required. This position will report to a Sr. Director or Director in Manufacturing Technology and will interact with Engineering, Manufacturing, Validation, Quality Assurance, Quality Control and Regulatory Departments. Interaction may be required with contract producers of the Company's products. Knowledge of cell culture, purification and support systems used in the manufacturing of biotech products is essential.

DUTIES AND RESPONSIBILITIES

The main areas of focus are purification and downstream processing activities. Author the required protocols, reports and regulatory documentation associated with the executed studies.

- Plan and manage the execution of process validation studies, such as process consistency studies, performed for our client's products.
- Author the required protocols, reports and regulatory documentation associated with the executed studies for the purification and downstream processing activities
- Review and approve protocols and reports authored by other groups.
- Author relevant portions of drug substance manufacturing and process validation sections of regulatory filings.
- Author technical reports supporting technology transfers, deviation/adverse event reporting and process analyses/trending. This responsibility is shared with the Process Sciences Group.
- Support the Manufacturing Process Sciences Group, the Statistics and Quantitative Sciences Group and the Clinical Manufacturing Group as required.
- Consult with other groups to troubleshoot manufacturing process problems.
- Ensures cGMP compliance.

REQUIREMENTS:

- BS degree in Chemical Engineering (equivalent non-engineering title for Biochemistry, Chemistry, Microbiology degrees).
- Minimum of 12 years experience in a GMP production/development environment.
- Has previously started-up and/or had a management role in a biotechnology facility.
- Has detailed process and equipment knowledge of protein purification processes and functions.
- Similar knowledge of cell culture processes a plus.
- Process validation experience required.
- Has a thorough understanding of cGMP requirements for a large scale manufacturing facility.
- Experience in successful facility licensure a plus.
- Excellent communication skills, both oral and written.
- Demonstrated supervisory skills.

Contact:

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Ashton Tweed, Ltd. helps companies nationally recruit and retain highly experienced talent on an Executive Search, Direct Hire and Interim Talent basis.