

Engineer II/Sr Engineer DS MSAT

Job ID: 00413148

Job Function

Production & Manufacturing

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Summary

This position is in the Drug Substance Manufacturing Science and Technology (MSAT) group, which supports cGMP manufacturing of both Clinical and Commercial products at Genentech's South San Francisco manufacturing facility. The group is responsible for monitoring, troubleshooting, and improving upstream and downstream unit operations from seed train through bulk formulation. In this position, you will need to provide scientific and technical judgment as part of a team responsible for delivering high quality biopharmaceutical products to patients. Integrity, accountability, and strong dedication to the patients we serve are critical to this role.

Job Responsibilities

- Adhere to all applicable compliance and safety requirements, cGMPs, SOPs, and other manufacturing documents.
- Provide manufacturing floor technical support
- Monitoring and analysis of manufacturing data as necessary to provide support for process discrepancies, investigations, validation protocols, process transfers, or equipment troubleshooting
- Data analysis and execution of experiments aimed at improving process robustness/productivity or meeting the changing needs of the manufacturing environment
- Implementation of engineering projects of various magnitude in order to increase levels of safety and/or compliance, improve process and equipment robustness, or increase capacity/productivity/efficiency.
- Support product impact and root cause assessments for process discrepancies and Quality investigations
- Support of regulatory inspections and filings
- Creation / revision of standard operating procedures and manufacturing tickets
- Training and technical mentorship of manufacturing operators
- Lead cross-functional technical teams on large scale improvement and compliance related initiatives

Who You Are

Job Requirements

General:

- Degree in Chemical/Biochemical Engineering or equivalent
- Knowledge of safety principles, quality systems, and cGMP
- Experience working in a cGMP environment
- Knowledge of large scale biopharmaceutical manufacturing processes and equipment
- Relevant work experience in a lab, pilot plant, manufacturing, or manufacturing support setting
- Candidate must be highly motivated, be able to work independently as well as in a team and have good organizational and oral and written communication skills.

Level Specific:

- Mastery of basic manufacturing, engineering and/or scientific theories, principles and techniques used in biopharmaceutical manufacturing processes.
- Assumes responsibility for process, equipment or technology development. Recommends and implements new technologies. Independently designs, executes and interprets results from trouble-shooting activities and small-scale studies. Monitors operations and is responsible for resolution of complex processing issues and manufacturing improvements.
- Works under general supervision. Work reviewed for soundness of approach

- Actively participates in group and project teamwork. Drives project / process improvements.
- Champions assigned projects. Justifies goals to colleagues. Acts as a mentor for those with similar or less expertise. Expected to lead cross-functional projects or teams.
- Contributions are integral to the achievement of PROP goals and production targets. Contributes to advances in technological capabilities.
- Prime contact both within and across work groups and with outside collaborators, regulatory agencies, and vendors on significant technical matters. Develops a network for technical issues within the industry
- Completes investigation, development and validation reports and drafts external publications where appropriate. Creates, reviews and approves manufacturing documents. Provides process and equipment knowledge and training to PROP and manufacturing partners.
- Contributes to regulatory filings. Effective communicator of ideas, project goals and results. Gives presentations across departments.
- Typically will have more than 5 years experience in industry or academia (including advanced studies) after receiving their Bachelors degree. Hiring and promotion into this position will primarily be based on demonstrated ability to fulfill the job requirements outlined above. The number of years of experience alone is not an adequate justification for hiring or promotion.

Work Environment/Physical Demands/Safety Considerations

As with any position in a manufacturing environment, the job requires an ability to adapt to rapidly changing priorities and the flexibility to support operations in accordance with the manufacturing schedule. Requires the ability to routinely access and work for extended periods of time in a cGMP facility, including adherence to all gowning and safety procedures.

Genentech is an Equal Opportunity Employer.