

Engineer II / Manufacturing Technical Specialist III, PTD / Global Biologics Manufacturing Science and Technology

Job ID: 00400945

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

- Lead and/or participate in tech transfers of purification processes across Roche/Genentech's drug substance manufacturing facilities and to external contract manufacturing facilities. Requires close collaboration with cross-functional team to implement, validate, and license Drug Substance processes at receiving sites.
- Responsible for providing on-going technical support for Drug Substance production at contract and partner sites. Includes monitoring process performance, resolving manufacturing deviations, participating in quality investigations, and providing technical approval of document and automation recipe changes to support continuous process improvement.
- Lead and/or participate in global initiatives and cross-functional teams in the areas of downstream processing.
- Work collaboratively with site Manufacturing Science and Technology (MSAT) groups to develop and communicate best practices for process design and operations to ensure consistency and compliance across the biologics manufacturing network.
- Represent MSAT Network on corporate initiatives led by partner groups such as Quality, Regulatory, Manufacturing Operations, Pharma Technical Development, etc.

- Provide technical leadership for topics including support for proposed manufacturing process changes, process validation, discrepancy and investigation evaluations, change control, and regulatory submissions. Some lab work may be required in order to resolve investigations and/or demonstrate proof-of-concept for proposed process changes.
- Responsible for authoring and reviewing technical reports, manufacturing instructions, process validation documents, and portions of regulatory submissions to support licensing processes at new manufacturing sites.
- Travel within the Roche network and to contract manufacturing sites will be required.

Who You Are

- BS/MS/PhD. In Chemical/ Biochemical Engineering or Life Sciences with at least 7-10 years relevant industrial experience in purification process development or in supporting manufacturing operations.
- Demonstrated experience with transferring processes and/or with process validation.
- Sound background in large-scale processing and engineering fundamentals as applied to purification processes.
- Motivated, able to work independently as well as in teams. Excellent organization and communication skills (both written and verbal).
- Demonstrated proficiency in leading teams, experience leading cross-site teams is a plus
- Proven ability to influence beyond direct line reporting relationships including to senior management.
- Experience with statistical tools and techniques for statistical process control and process troubleshooting methodologies (SAS JMP, Excel).

Genentech is an Equal Opportunity Employer.