

Sr. Engineer/Sr. Manufacturing Technical Specialist, Biologics Manufacturing Science and Technology, Drug Product

Job ID: 00411069

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

This position is part of the drug product group within Biologics Manufacturing Science and Technology (BMSAT) organization. The successful candidate will work with a team of engineers and manufacturing technical specialist responsible for fill-finish technology transfer to contract/partner manufacturing sites, as well as process transfer between Genentech/Roche manufacturing sites. The successful candidate will also be responsible for providing ongoing technical support for drug product manufacturing processes across the Genentech/Roche network. Candidate will ensure technical stewardship across the various CMO product transfers as well as ongoing continuous improvement projects.

- Serve as a technical lead for one or more fill-finish process transfers to contract/partner manufacturing sites, as well as between Genentech/Roche manufacturing sites.
- Provide on-going fill-finish manufacturing support to the CMO or internal manufacturing sites by performing trouble shooting, product impact assessments during deviations and investigations and process improvements.
- Work collaboratively with the site MSAT groups, Late Stage Pharmaceutical Development groups, Manufacturing Operations, and Engineering to develop in-depth knowledge of the fill-finish processes and to facilitate technology transfers.
- Author and review technical reports, process validation documents, and portions of

- regulatory submissions to support licensure.
- Identify and communicate manufacturing best practices, and work to ensure manufacturing process consistency across the different fill-finish facilities.
- Lead and participate in cross-site and cross-functional teams responsible for technical oversight of drug product manufacture and process improvements, developing global standards, troubleshooting issues, analysis of cross-site process performance data and implementation of quality standards.
- Lead and/or guide the product technical teams (PTTs), serve as a member of the PTT, collaborate closely with the product supply chain, quality and regulatory lead. Participate in Joint Management Teams (JMT) for CMO transfers for functional representation and/or team updates.

Who You Are

- BS/MS/PhD in Biochemistry, Biology, Chemical Engineering, Bioengineering or Pharmaceutical Technology or related discipline.
- Approximately 8 years (including advanced studies) of experience in fill-finish process development and/or manufacturing support with extensive practical knowledge of fill/finish manufacturing processes. We are looking to hire a recognized authority in the field of drug product processing.
- Strong background in the relevant unit operations including mixing, formulation, sterile filtration, sterilization, aseptic processing, component processing technologies, filling, lyophilization and visual inspection.
- Development and manufacturing experience related to primary packaging components is highly desired.
- Prior experience with large-scale fill-finish equipment, technology transfers, process validation and risk assessments is a plus.
- Familiarity with protein handling and processing considerations.
- Highly motivated individual with proven collaboration skills and the ability to work in a team as well as independent environment.
- Excellent communication skills, both written and verbal, effective communicator of ideas, project goals and plans.
- Language expertise- in addition to English, working knowledge of one other international language (Example, German, Russian, Portuguese, Spanish) is highly desirable.
- Proven ability to effectively deliver results to a diverse stakeholder and customer group.
- Willing to travel (10-40% of time).

Genentech is an Equal Opportunity Employer.