

Cell Culture Engineer II / Manufacturing Technical Specialist III, Global Mfg Science & Technologies

Job ID: 00414611

Job Function

Biologics Drug Substance Production

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 is an exciting opportunity within the Drug Substance Global Biologics Manufacturing Sciences and Technology (DS GBMSAT) department in the Pharma Technical Development organization. GBMSAT provides technical leadership to develop solutions in support of commercial manufacturing across the internal and external Roche network. GBMSAT plays a critical role in enabling the network concept for the MSAT network across Roche.

Additionally, GBMSAT provides technical leadership for technology transfers to contract manufacturing organizations.

Responsibilities:

- Provide technical support for 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.

- Facilitate product introductions into Contract and Roche partner manufacturing, as well as technology transfer between Roche Biologics Drug Substance Manufacturing sites.
- Responsible for authoring technical reports, manufacturing instructions, process validation documents, and portions of regulatory submissions to support licensing processes at new manufacturing sites.
- Responsible for providing ongoing technical support for processes that are currently being manufactured at contract and partner sites. Includes support of discrepancies, investigations, and change control; process data review; and representation of external sites on Product Technical Teams.
- Participate in global initiatives and cross-functional teams comprised of subject matter experts in the areas of commercial process stewardship, best practice development, troubleshooting and manufacturing innovation.
- Work collaboratively across the MSAT network to identify and communicate standards and best practices for process design and manufacturing to ensure consistency across the biologics cell culture manufacturing facilities.
- Travel within the Roche network and to contract manufacturing sites will be required.

Who You Are

Requirements:

- BS/MS/PhD. In Chemical/ Biochemical Engineering or Life Sciences with at least 5 years relevant industrial experience in cell culture and/or E. coli process development or in supporting manufacturing operations.
- Demonstrated experience with technology transfer and/or with process validation.
- Sound background in large-scale processing and engineering fundamentals as applied to cell culture processes.
- Motivated, able to work independently as well as in teams. Excellent organization and communication skills (both written and verbal).
- Experience with statistics in the areas of statistical process control, modeling and data management is a plus.
- Experience with tools and techniques of formal process management and improvement methodologies (Operational Excellence, Class A) a plus.

Genentech is an Equal Opportunity Employer.