

## **Sr. Technical Manager, Tech Transfer – Biologic Drug Substances**

Job ID: 00414277

### **Job Function**

Quality

### **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**

(External Quality, Commercial Drug Substance)

Sr. Technical Manager, Tech Transfer – Biologic Drug Substances (SSF)

Main Purpose of the Position:

- \* Provide Quality oversight for Roche and Genentech products manufactured at Contract Manufacturing Organizations (CMOs) to ensure compliance with cGMP regulations and Roche/Genentech standards.
- \* Serve as the Quality single point of contact for designated CMO(s) and participate as a key member of Drug Substance (DS) CMO governance teams to support site selection, product technical transfers and on-going external commercial site management.

Responsibilities:

- \* Participate in site selection and product technical transfer activities at CMOs, such as due

diligence audits and GMP readiness activities.

- \* Manage all required activities to support release of commercial product including approval of master process documentation, batch record review, resolution of investigations, and assessment of change controls.
- \* Develop, negotiate and maintain CMO cGMP quality agreements and ensure compliance with agreements.
- \* Develop/maintain quality risk management plans; utilize risk management tools to identify and mitigate CMO quality and compliance risks, ensuring CMO sites are in a state of continuous inspection readiness.
- \* Participate in regulatory inspections and cGMP compliance audits, collaborating with CMOs to ensure on time closure of associated CAPAs. Support regulatory filings for products manufactured at CMOs.
- \* Support creation of Annual Product Reviews, product complaint investigations, and other quality functions as required.
- \* Establish CMO goals/metrics and monitor and report progress. Lead or participate in CMO or cross-functional process & quality improvements projects.

## **Who You Are**

- \* B.A. or B.S. degree (preferably in life sciences or engineering) and 8-11 years experience in the biopharmaceutical or related industry, or an equivalent combination of education and experience.
- \* Hands on expertise in one or more technologies in biopharmaceutical drug substance or API manufacturing with working knowledge of facility, equipment and process qualification/validation.
- \* Working experience with risk management concepts and tools.
- \* Sound knowledge of cGMPs and relevant international regulatory requirements and experience in Quality Assurance with ability to accurately interpret and implement quality standards.
- \* Well developed teamwork, collaboration and negotiation skills and ability to communicate clearly and professionally both verbally and in writing.
- \* Demonstrated problem solving and decision making skills.
- \* Travel is required between 20-40%, both domestically and internationally; international working experience and multiple language proficiency is desired.

Genentech is an Equal Opportunity Employer.