

## Senior Technical Manager, EQA

Job ID: 00403895

### Job Function

Quality Assurance

### 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

### Main Purpose of the Position:

- Support the development, implementation and management of the overall environmental control program in SSF Drug Substance and Drug Product Manufacturing following, cGMP regulations, Genentech and Regulatory requirements.
- Provide Quality oversight from and critically evaluate EM issues, discrepancies, Media Fill data, airflow evaluations, and assess facility/process changes.
- Develop solutions to complex issues and Quality initiatives with inter-organizational impact.
- Perform tasks and work to achieve company goals and organizational objectives.

### Technical Duties/Responsibilities:

- Provide oversight of the Environmental Monitoring (EM) program ensuring consistency with company/regulatory policies and procedures.
- Present and provide rationale of EM program during periodic audits and regulatory inspections.

- Provide input in the preparation of regulatory submissions.
- Provide input into investigations involving suspect equipment, utility or facility failures resulting from EM activities.
- Provide Quality oversight throughout the Drug Substance and Drug Product Manufacturing areas.
- Provide technical assessment and approval for changes to the EM program.
- Collaborate with departments to ensure that EM activities are executed efficiently and effectively.
- Provide oversight to the Media Fill program and create Media Fill protocols and summary reports.
- Execute Airflow Visualization studies and create summary reports.
- Provide guidelines for area/system Shutdown Authorization Request (SAR) activities.
- Ensure proper policies and procedures are established to guide EM efforts.
- Ensure department representation on relevant project teams.
- Identify, design, and implement environmental monitoring process improvements.
- Communicate group performance against established metrics to Quality Management.

## **Who You Are**

### **Qualifications: Education, Experience, Knowledge and Skills:**

(Minimum requirements)

- B.S./B.A./M.S./M.A. degree (preferably in Microbiology) and at least eight years experience in the pharmaceutical, biopharmaceutical or related industry, or an equivalent combination of education and experience
- Experience with Drug Substance and/or Drug Product filling preferred
- Sound knowledge of cGMPs and equivalent regulations
- Ability to interpret and relate Quality standards for implementation and review
- Ability to make sound decisions about and managing priorities
- Ability to communicate clearly and professionally both in writing and verbally
- Flexibility in problem solving, providing direction and work hours to meet business objectives

\*LI-BM1

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