

Engineer II/Sr Engineer, Validation

Job ID: 00411210

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

Responsibilities: This position is for a Validation Engineer reporting to a Manager of Technology Validation in the South San Francisco Production Technology Department. The candidate will be responsible for Validation scope supporting the South San Francisco manufacturing plants. This includes drafting and execution of validation protocols, authoring validation and technical reports and development of project plans. In addition, the candidate will support technical assessments for quality impact and participate on quality investigation teams. The candidate will also monitor maintenance of the validated state of basic and some complex equipment and processes. This includes monitoring operations and resolving moderate validation issues. The candidate will support introduction of clinical products into manufacturing by participating on campaign/product planning teams and delivering the appropriate validation activities consistent with project timelines. The candidate may lead cross functional teams or projects. The candidate will be expected to work effectively in teams, to influence others to generate support for assigned activities or projects and to justify goals to department colleagues. They will also act as a mentor for those with similar or less validation expertise.

Who You Are

Requirements: A B.S or higher in Chemical, Biochemical or Mechanical Engineering or Science discipline with 5-8 years of relevant experience for the Engineer 2 level. 8 plus years

experience required Sr Engineer consideration. The candidate must have work experience in a GMP regulated environment and a basic understanding of biopharmaceutical processes, equipment and facilities with demonstrated advanced knowledge of at least one biopharmaceutical unit operation or aspect of Validation. Also must have a demonstrated capability to use quality systems and processes such as change control and discrepancy/deviation processes. The candidate must have a passion for customer service to the diverse cGMP manufacturing customers as well as the MSAT and quality organizations. Knowledge and application of basic validation and risk management theories, principles and techniques used in biopharmaceutical manufacturing is highly desirable.

The candidate must be highly self motivated, have excellent organization and communication skills, be willing and able to work independently and as part of a multi-disciplinary team. The candidate must be comfortable with change and be willing to establish and work towards the future vision for the organization.

Physical Requirements: The candidate must be able to lift and carry 25 lbs. The candidate must be able to climb and descend stairs. The candidate must be able to don gowning as required to enter GMP facilities. The candidate must be able to stand in the manufacturing environment for several hours.

Genentech is an Equal Opportunity Employer.