

Senior Materials Analyst

Job ID: 00414647

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

Summary

Responsible for producing innovative Biotherapeutic medicine by interfacing with production systems and controls in a cGMP manufacturing environment, maintaining areas of responsibility in a high state of inspection preparedness, managing the performance of both manual and semi - automated warehouse processes to support manufacturing unit operations, collaborating with the network to implement multi-site process improvement initiatives/CAPAs and executing department objectives to support strategic goals. Partners with the business to deliver business results focused on establishing and improving business processes to improve reliability, increase simplicity, and enable growth, while utilizing a DMAIC data-driven, problem solving methodology to deliver tangible business results. Responsible for business process analysis, design and optimization to enable the routine delivery of exceptional performance.

Job Responsibilities

Applies a complete understanding of theories and concepts from one's technical/professional discipline to independently address a broad range of difficult problems. May determine

methods and procedures on new assignments.

Essential

- ¿ Manage and resolve technical and compliance issues with Quality, Maintenance, Calibration & EH&S.
- ¿ Lead teams to execute internal/cross functional and network related projects that may include investigating, analyzing, formulating solutions, identifying improvement opportunities, documenting processes, training, process/system performance improvement and cascading results to management.
- ¿ Partnering with the customers, communicating/coordinating/bringing together key stakeholders, and delivering real value-add sustainable solutions.
- ¿ Act as SPOC for compliance or regulatory agency issues within the department
- ¿ Identify the technical, procedural and equipment issues that may compromise production and compliance, working closely with cross functional / network groups to identify and implement solutions.
- ¿ Implement and follow through on corrective and preventative actions for variances or regulatory observations.
- ¿ Represent the department in reviewing and approving all production related documentation requiring approval such as process validation protocols and final reports, planned and unplanned variance reports, documentation change requests, engineering and facility change requests, and validation protocols.
- ¿ Supports department to meet corporate goals and department objectives.
- ¿ Representing the department as the change agent.
- ¿ Deliver project goals on budget and on schedule.
- ¿ Make recommendations to Management based on business case and analyses.
- ¿ Lead decision making support and make recommendations regarding best options.
- ¿ Communicate proactively with stakeholders regarding progress, issues and plans for resolution.
- ¿ Develop and use project plans to coordinate participants and track and report progress.
- ¿ Ensure improvement methodology and tools are utilized effectively to maximize benefits.
- ¿ Operate with a high degree of autonomy and professionalism; successfully prioritize workload in accordance with business goals.
- ¿ Ability to identify problems, define problem statement clearly and accurately and apply structured and disciplined methodology to identify data-driven root causes.
- ¿ Innovative and effective in solution development, risk mitigation, and execution.
- ¿ Work collaboratively with network to implement multi-site process improvement/CAPAs to mitigate compliance related risks.
- ¿ Ensure that all operations are performed with 100% compliance to documentation cGMP standards.
- ¿ Ensure maintenance of a safe warehousing work environment that complies with company and state regulations.
- ¿ Submit reports and compile data for trending and identifying problem areas.
- ¿ Collaborate with other departments to address issues and meet deadlines.
- ¿ All employees with jobs that require access to the Warehouse must be able to pass the Transportation Security Administration (TSA) Security Threat Assessment (STA).
- ¿ Ensures the integration of environmental health, safety, and security into the business processes, systems, and programs while reporting safety and environmental incidents including injuries, illnesses, and safety suggestions within one's functional area. Fosters a

positive safety culture in which no one gets hurt.

Who You Are

Job Requirements

Education and Experience

- ¿ BS/BA in Science or Engineering or 6-8 years equivalent experience.
- ¿ MS or MBA or 4-6 years business/operations experience.
- ¿ Certified/Expertise in proven methodologies such as: LEAN / Six Sigma a plus.
- ¿ Minimum 2 years of related analytical, business and operational experience in Supply Chain Management /Manufacturing / Engineering or Process Development. APICS and cGMP expertise preferred.
- ¿ Minimum 2 years of project management experience required.

Knowledge, Skills and Abilities

- ¿ Demonstrates a high level of professionalism, efficiency, conflict resolution, and follow-through
- ¿ Proven presentation and facilitation skills with the ability to present issues both informally and formally.
- ¿ Excellent communication skills, verbal and written.
- ¿ Demonstrated ability to manage multiple activities while maintaining a high level of organization.
- ¿ Demonstrates initiative; ability to undertake additional responsibilities and respond to situation as they arise with little or no supervision.
- ¿ Able to work effectively in a customer service and business partner role.
- ¿ Ability to work as part of a team and collaborate effectively with staff at all levels.
- ¿ Ability to work independently in achieving goals and objectives.
- ¿ Biotech / pharmaceutical industry experience a plus.
- ¿ Familiarity with ICH and European guidelines.
- ¿ Possess thorough knowledge and understanding of cGMPs and familiarity with FDA guidelines.
- ¿ Knowledge of Warehouse inventory processes and cold chain management
- ¿ Proficiency with the following software: Microsoft Word, Excel, and Project.
- ¿ Manage assignments that are complex in nature where independent action and a high degree of initiative are required in resolving problems and developing recommendations.
- ¿ Knowledge of Manage Logistics and Distribution processes

Work Environment/Physical Demands/Safety Considerations

- ¿ Ability to work off hours and adjust schedule beyond normal 8am to 5pm workweek to support a 24X7 operation.
- ¿ Expected to be on feet for 8 to 10 hours a day.
- ¿ Climb upwards of 6 flights of stairs a day to maneuver within the manufacturing facility.
- ¿ Lift up to 25lbs may be required.
- ¿ Environment requires that gowning in the form of hospital scrubs, bunny suits, gloves and steel toe boots be worn.
- ¿ Work in clean room environment with large mechanical equipment, piping, and pumps connecting to tanks serviced by high-pressure steam, water and air.

¿ May work with hazardous materials.

Genentech is an Equal Opportunity Employer.