

Associate Director, Biologic Investigations

Job ID: 00412153

Job Function

Management 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

Main Purpose of the Position:

- Direct staff and operations to manage and support multi-site investigations and CAPAs.
- Provide leadership and guidance to staff performing multi-site investigations and CAPA activities for the Biologics OU.
- Establish strategic goals and objectives to achieve department and company
- Manage performance and development of direct reports to ensure achievement of organizational and department goals and a productive environment.

Job Duties/Responsibilities:

- Manage and administer all aspects of people processes related to the employee life cycle. This includes the selection, hiring and training of personnel on company and department policies, systems and processes. Manage and communicate compensation related information per company guidelines.
- Coach and develop staff by providing an environment that encourages ongoing personal and professional growth. Manage and ensure the setting of realistic personal goals for staff and provide regularly scheduled feedback throughout the year. Ensure staff receives appropriate knowledge and skill development and growth opportunities.
- Interpret, execute and recommend improvements to Quality operational policies, plans and procedures.
- Provide input to department budget and monitor and control expenditures against the

department budget.

- Provide input for the development of overall Quality objectives and long-range goals.
- Notify Senior Management of potential quality or regulatory issues that may impact product quality or regulatory compliance.
- Lead and participate in continuous improvement initiatives for Genentech Quality Systems.
- Sign documents for activities as authorized and described by Genentech policies, procedures and job descriptions.
- Be accountable for behaviors described in the Roche Leadership capabilities.
- Perform any other tasks as requested by Senior Management to support Quality oversight activities.

Technical Duties/Responsibilities:

- Lead a team to manage and support multi-site Biologic investigations and CAPA.
- Support the development and manage the implementation of the Investigator Certification program.
- Sponsor and provide guidance for multi-site investigations and CAPA activities.
- Participate in the Quality review Board
- Develop and report metrics that focus on continuous improvement and ensure an effective and compliant investigation system.
- Partner with Site Quality Heads and other PT groups to with interdepartmental contacts on investigation assessment, resolution, and quality approval.
- Approve Quality Investigation.
- Perform timely escalation to Sr. Management of quality issues potentially impacting products, materials or processes
- Support sites during root cause analysis
- Lead Investigation and CAPA continuous improvement efforts
- Develop short-term goals and long-range plans to ensure effective utilization of Quality resources to support
- Act as an advisor to internal project teams by providing extensive knowledge of regulatory requirements, industry standards, and company strategy.
- Provide technical and quality assurance input during the review and approval of applicable documents.
- Participate in the Quality Review Board.
- Manage the end-to-end investigation process
- Identify, facilitate and establish cross-site and cross-business unit processes to ensure efficient and timely investigation strategies.
- Ensure appropriate application and integration of cGMPs into the discrepancy management system.
- Educate departments on the best practices for conducting investigations and root cause analysis.
- Collaborate with departments to ensure process improvement proposals are practical and feasible.

Who You Are

B.S. or B.A. degree (preferably in Life Science) and twelve years relevant experience in the pharmaceutical or biopharmaceutical industry

- Strong knowledge of Biotech manufacturing operations and Quality Systems.
- Sound knowledge of cGMPs
- Ability to interpret and relate Quality standards for implementation and review
- Demonstrated ability to manage and make sound decisions about scheduling, allocation of resources, managing priorities, and Quality issues.
- Demonstrated knowledge and execution of Quality operations and processes

- Experience in directing and leading successful quality organization functions
- Ability to interpret and relate Quality standards for implementation and review
- Ability to communicate clearly and professionally both in writing and verbally
- Flexibility in problem solving, providing direction and work hours to meet business objectives
- Ability to work collaboratively across a global organization
- Demonstrated ability to influence others

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