

## Senior Country Study Manager-gMED

Job ID: 00414052

### Job Function

Clinical Operations

### 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

The Country Study Manager (CSM) provides leadership to one or more Study Management Teams (SMTs) and provides strategic planning and organization to achieve successful study completion. The CSM maintains full ownership of the US Medical Affairs portion of a study and ensures the effective and efficient delivery of the operational aspects in accordance with the medical plan and ICH/GCP standards, Roche SOPs, local operating guidelines and local regulatory requirements. The CSM also ensures the development and maintenance of productive relationships with our customers.

### Responsibilities:

- Provides Direction and Leadership to one or more SMTs
- Establishes Study Timelines, Budget, Resource, Risk and Quality Plans
- Manages the Delivery of Study Activities in Order to Meet Study Plans
- Builds effective, high performing SMTs through influence, integration, motivation and

optimization of team performance.

- Develops and maintains effective working relationships with, and is the primary contact for, key stakeholders, eg, Pharma Business
- Functions as Study Management Team Leader.
- Maintains awareness of external clinical research practices to ensure the SMTs are aware of the risks, priorities, value and impact of their work and contributions.
- Provides input into the study synopsis, development of the final protocol, feasibility conduct and all study specific documents and procedures.
- In accordance with the overall medical plan, establishes and maintains accurate study level plans in designated resourcing and planning system.
- Is accountable for the development and active management of the study patient recruitment strategies in US Medical Affairs.
- Develops Partnership with Business, participates on local life cycle teams, consults local Business Units, and participates in local Business Unit meetings as necessary.
- Is accountable for the selection, training and direct management of external suppliers supporting US Medical Affairs trials.
- Ensures that data is delivered in accordance with established dataflow timelines.
- Develops/maintains investigator relations, builds and maintains a professional relationship between Roche and Investigator, participating in Investigator Meetings as necessary.
- Monitors progress against SMT goals and takes appropriate action to ensure goals are met and issues are communicated with the appropriate persons or teams.
- Oversees the management of the Clinical Operations studies budget.
- Leads the evaluation of standards across one or more SMT(s) with the objective of enhancing quality, productivity and efficiency.

## **Who You Are**

Requirements:

- Bachelors degree in a medical/science-related field with minimum of 5 years proven experience in Clinical Research/Development
- Proven clinical development experience on operational aspects of conducting clinical studies including: vendor/CRO management, leading/working as part of a development team, implementing clinical development/medical plans and coordinating study level activities to deliver data for filing or publication purposes
- Demonstrate experience in project management including implementation of risk

management plans and management of complex study budgets and resourcing plans

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