

Associate Medical Director/Medical Science Director Actemra Medical Affairs

Job ID: 00410734

Job Function

Medical Information

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

MSDs are generally expected to perform their responsibilities with limited guidance from Medical Directors and/or other relevant internal partners and stakeholders:

- Implement the medical affairs plan for the assigned drug(s) /indication(s), working with Medical Directors, mainly on PhIV clinical programs and their publication plans
- Collaborates with Commercial and provides scientific input for the development and review promotional materials, documents and presentations developed for the assigned drugs and/or indications (signing off of any promotional material remains the responsibility of the Medical Director of the assigned drugs and/or indications)
- Support his/her manager, as and when requested, in developing relevant parts of the medical affairs tactical plans, and/or completing other special projects such as preparation and review of training materials for field forces
- Demonstrate ever-increasing competence in implementations of all aspects of medical plans
- Competently and collaboratively interact with a host of internal and external partners

and stakeholders

- Consistently complete all assigned responsibilities on-time and on-target.
- Develop and cultivate important relationships with internal and external partners and stakeholders. Includes investigators, thought leaders and KOLs (key opinion leaders)
- Stay informed and abreast of the external landscape as it relates to assigned drugs and/or indications and the associated therapeutic area(s)

JOB DESCRIPTION - PRIMARY DUTIES AND RESPONSIBILITIES:

1. Clinical Trials & Programs

Provides clinical oversight for a variety of projects, in consultation with his/her Medical Director or Senior Medical Director :

- Works with a host of internal and external partners and stakeholders in the implementation of clinical trials for assigned drugs/indication
- Provides scientific input into and/or coordinates the development of specific clinical trial documents for review and discussion with Medical Directors* (e.g., protocols, charters, safety monitoring plans, process documents, etc.) including disease and/or treatment registries
- Participates in the identification of appropriate external investigators
- Oversees the clinical trial implementation, ongoing monitoring and evaluation, working closely and regularly with external investigators and Clinical Operations. Active Member in Study Management Team for assigned drugs/indications
- Develops and cultivates relationships with external partners such as clinical investigators, clinicians, scientists and KOLs, as well as cross-functional partners in GNE Medical Affairs, Clinical Development, Commercial, Legal and Regulatory.
- Supports his/her manager in developing clinical components of presentations* for clinical trial investigator meetings
- In collaboration with his/her manager, coordinates the preparation and reviews data outputs for reporting documents* where appropriate (e.g. clinical study reports, analysis plans, etc.) with the CRO, the Medical Affairs Biostatisticians and his/her Medical Directors
- Monitors project progress and is expected to proactively identify any issues or challenges and recommend and implement strategies to effectively resolve such once approved with his/her manager
- Works closely with his/her manager, the publication team and Clinical Operations to

complete associated publications, reviews draft publications*.

- Keeps all partners abreast of projects progress throughout all applicable intervals
- May also participate/coordinate collaborations with external stakeholders

(e.g. cooperative groups, other companies, etc.) on development and implementation of approved clinical projects.

- May coordinate, liaise with internal and external providers for data mining activities
- Helps his/her manager provide data outputs requested for safety and/or other relevant sections of IND annual reports, if these sections and reports relate to assigned drugs and/or indications*.
- May interact with NCI or other agency, as appropriate, with supervision from his/her manager

¿ Stays abreast of internal and external developments (scientific, clinical, commercial, competitive, legal, regulatory and like) as such developments may implicate or otherwise impact the implementation of the medical plan of the assigned drug(s)/indication(s). Includes attendance at major scientific conferences, participation in competitive intelligence activities, and review of published literature

* sign off of these materials remains the responsibility of the Medical Director

2- Post marketing/Commercial activities

¿ Reviews and/or helps creating clinical materials* (including presentation slides) by providing scientific input and checking for data accuracy, to support post-marketing and commercial activities. This may include commercial advisory boards such as community advisory boards, regional advisory boards and the like. May present clinical information at commercial advisory boards

¿ Reviews training materials and slides*, and provides clinical input and guidance in their development.

¿ if deemed appropriate by his/her manager, represents his/her assigned Drug(s)/Indication(s) to some cross-functional forums, e.g. Genentech's Promotional Review Committee, Grant Review Committee, etc.

¿ may train GNE sales forces on clinical matters under the supervision of his/her manager as these relate to marketed drugs, relevant disease state, approved indications, dosage, risk and safety profiles and the like

¿ Supports Medical Communications, as and when needed and appropriate, to "triage" external communication, reviews draft materials* and related information prepared for

external distribution

* sign off of these materials remains the responsibility of the Medical Director or associate Medical Director

3. Departmental Support & Personal Development

- ¿ Helps on-board, coach and mentor new and/or less experienced staff members
- ¿ Participates in and/or leads special Franchise/departmental projects
- ¿ May support Franchise planning and budgeting; helping his/her manager to gather data/analyses and prepare for expense budgets or other planning processes
- ¿ Solicits ongoing internal and external partner/stakeholder feedback on his/her performance and uses to continuously fine-tune and hone his/her approach, work and results
- ¿ Participates in various internal and external training or other development opportunities
- ¿ Identifies and recommends process and other improvements; whether pertinent to his/her specific department and/or beyond
- ¿ Prepares for and actively participates in GNE's Performance Planning & Review Process
- ¿ Takes an active role in personal career development
- ¿ Participates in various staff meetings, including regular one-on-one meetings with his/her manager

Who You Are

Education, Experience, Knowledge and Skills (Minimum Requirements)

- Strong science/clinical background with advanced degree (e.g. MSN, M.D., Pharm.D., Ph.D.)
- Minimum of 5 years experience as a clinician and/or in clinical research.
- Minimum of 5 years in pharmaceutical industry
- Demonstrated leadership competence
- 3 years experience in MSL or related role (preferred)
- Minimum of 3 years experience in role-specific therapeutic area
- Excellent interpersonal, leadership, and communication skills
- Willingness to travel

Genentech is an Equal Opportunity Employer.