

Manager/Sr. Manager - Companion Diagnostics

Job ID: 00410908

Job Function

Development

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Manager

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

We are seeking a highly motivated individuals to join the Oncology Biomarker Development Dept. to lead companion diagnostic (CDx) development programs in support of the Roche / Genentech early and late stage Oncology clinical development pipeline. The incumbent will provide leadership for a portfolio of molecules within a Franchise and represent these programs to senior management and decision-making bodies internally.

The CDx development strategies will be closely aligned with clinical development program timeline and strategy to enable robust clinical validation of the CDx, including establishment of thresholds and statistical analysis of the relationship with efficacy or safety using robust assays developed with diagnostic partners. The incumbent will also develop cross- functional relationships with internal scientific, operational and regulatory groups and diagnostic partners, and represent GNE / Roche CDx efforts to external professional organizations and regulatory bodies. The successful candidate will also be expected to contribute to Medical Affairs strategies to enable biomarker hypothesis testing.

Responsibilities

- Work closely with the biomarker, regulatory, statistics and clinical leadership to ensure

development and effective operational execution of the CDx portfolio of multiple investigational agents in Franchises or Disease Area

- Management of direct and matrixed reports whose responsibilities will include programs in both early and late stage clinical development. A substantial focus will be in early development where design of CDx strategies that enable device development in preparation for hypothesis testing will be important. Therefore requires strong understanding and experience with development of diagnostic devices in order to develop fit for purpose CDx strategies.
- Develop and lead strategic initiatives to identify novel CDx technologies and develop relationships to enable effective evaluation of technologies as CDx assays.
- Develop and lead IVD strategies that are aligned with disease areas including development of multiplex platforms to support investigational and approved products in collaboration with diagnostic partners.
- Enable the coordination and execution of exploratory biomarker hypothesis testing in the clinic.
- Develop relationships with external key investigators, scientists and professional organisations in the diagnostic technology field to inform internal CDx strategies including next generation technology implementation and validation.
- Represent CDx strategy to health agencies as part of the regulatory strategies for the agents within the entire portfolio.

Who You Are

PhD or MD/PhD degree with research experience in Oncology, preferably in a translational context.

- Post-doctoral experience in technology development or translational research is preferable
- Highly experienced in biomarker / companion diagnostic development with a proven track record of excellence during 5+ years of experience in an industrial Oncology development context.
- Strong understanding of technology and IVD development is required.
- Demonstrated experience in companion diagnostic development and IVD development preferred and understanding of the regulatory requirement for approval of a companion diagnostic both from the device and clinical development perspective
- Strong understanding of the operational considerations in executing biomarker and companion diagnostic strategies in clinical development is required.
- Strong track record of publications in clinical research as well as contribution/authorship of documents for regulatory submission.
- Outstanding presentation and communication skills; ability to
- Lead, influence, and motivate others
- Distill complex issues and clearly articulate / present solutions
- Ability to work across different cultures
- Ability to travel up to 20%, including domestic and international travel

Genentech is an Equal Opportunity Employer.