

Head of T-cell Engineering - Process Development, Analytical and Product Control

Job ID: 201901-100898

Job Function

Operational Excellence

Location

South San Francisco
California
United States of America

Schedule

Full time

Job type

Regular

Company/Division

Pharmaceuticals

Job Level

The Position

Genentech is inviting applications for an exciting leadership role in a newly established T-cell Engineering and Development Department within Pharmaceutical Technical Development, US Biologics. Genentech is committed to develop personalized and T-cell-directed therapies to treat patients with cancer. As one building block of this commitment, Genentech is collaborating with Adaptive Biotechnologies, a leader in immune-sequencing, identification, and selection of personalized T-cell receptors against shared and private neo-antigens.

The successful candidate will have the opportunity and responsibility to establish an end-to-end CMC capability for an engineered T-cell Therapy. This includes but not limited to T-cell isolation and engineering, process development, automation, manufacturing, product control, and T-cell characterization (in collaboration with our Cancer Immunology research group). New and innovative approaches will be welcome.

The successful candidate will:

- Interface and work effectively with internal stakeholders such as Genentech Research and Early Development (gRED), Pharma Technical Development, Regulatory, and Quality, and foster strong external collaborations with our partners, CMOs, and health authorities.
- Establish T-cell isolation, engineering and propagation processes, develop analytical capabilities and lead an agile and dynamic T-cell Therapy development group by collaborating and integrating with the Project Core Team comprised of colleagues from research, biomarker, PK/PD, regulatory and clinical sciences.
- Direct IND and BLA/MAA authoring and ensure the quality of development studies, reports and regulatory documents.
- Build an innovative, robust, and industry-leading T-cell Therapy platform to ensure successful commercialization globally with competitive COGS and reliable supply.
- Contribute to Roche/Genentech long-term strategy and capabilities in Cell and Gene

Therapy.

Qualifications

- PhD, MD, or DVM in immunology or related discipline.
- 10+ years of relevant experience with 5+ years in a Biopharmaceutical setting.
- Strong expertise in *in vitro* molecular biology, including genetic engineering and cellular immunology assays, including flow cytometry and molecular characterization.
- A track-record in process development and T-cell manufacturing approaches under cGMP with commitment to quality and compliance.
- Authorship in INDs, BLAs, and MAAs in the areas of T-cell therapy.
- Proven industry leader with influence in cancer immunology and T-cell therapy.
- Demonstrated leadership with strong communication skills and an ability to deliver results through teamwork.
- High learning agility with demonstrated critical thinking and problem solving skills with the ability to evolve and adapt under challenging situations.

#LI-PTD-JM1

Who We Are

A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our [Genentech Careers page](#).