We are a fast-growing, clinical-stage biopharmaceutical company developing tumor-specific T cell receptor (TCR) therapies. Our dynamic, international team sets out with the ambitious goal to revolutionize the TCR landscape using our unique and proprietary transgenic HuTCR mouse platform to produce off-the-shelf, fully human TCRs for the treatment of cancer. To achieve this ambitious goal, we have successfully completed Series A financing with top-tier investors in August 2020.
Our lead TCR program is currently prepared for Phase I clinical development in patients with solid tumor. Moreover, we plan to advance further programs into the clinic, ramping-up preclinical work for additional selected proprietary pipeline candidates and discovering TCRs against novel targets.

To achieve our goals, we are looking for a

Executive Director / Vice President, Global Quality

Role

The Executive Director / Vice President, Global Quality position is an important new role in T-knife's expanding global cell therapy company. Reporting to the SVP, Chief Operating Officer, this role is responsible for building out a world class quality organization at T-knife. Articulate issues and concerns to senior / executive management in a constructive, clear and actionable manner; using metrics and data. Focus will be on establishing quality throughout all applicable operations at T-knife, oversight of all external CRO, CMO, contract laboratories and critical starting material manufacturer activities, including but not limited to providing quality leadership for tech transfers between sites and CRO/CMOs, supporting major/critical investigations, regulatory filings, and supporting inspections. This position will also be responsible for the team establishing all internal quality standards (quality manual, quality systems, site master file, master plans, etc.) as well as review and approval of applicable standard operating procedures (SOP's), CAPAs. change control documents, production batch records, batch release documents, etc. This includes responsibility to ensure all operational related activities at the vendors (CRO, CMO, and other) are conducted to meet all T-knife's requirements.

Responsibilities

- Create, collaborate, lead, and enforce a culture of quality throughout the company to help ensure compliance with all applicable regulations, corporate standards, policies, and procedures
- Establish strategic goals for Quality and communicate these to QA and relevant internal customers in a spirit of shared partnership, motivating others through personal leadership and credibility
- Develops phase appropriate quality models in accordance with a risk-based compliance approach
- Provides leadership, mentoring, and coaching for the subordinates on the Global Quality team; supporting their career development in line with the business needs

- Identifies critical compliance and/or business issues related to CROs, CMOs, Contract Laboratories, and manufacturers of critical starting materials. Creates remediation strategies and tactical plans as needed using a risk management-based approach.
- Partners with internal Stakeholders: EU and US Operations, Manufacturing, Research, Clinical Development, Program Management, Regulatory Affairs, G&A, etc.
- Collaborates with External Partners: CROs, CMOs, Contract Laboratories, and critical starting materials manufacturers to ensure quality and uninterrupted operations
- Supports the major/critical deviations and events investigations minimizing risk on product quality, efficacy, and safety.
- Manage the development and reporting of Quality metrics and periodic reporting describing compliance trends and any areas of risk with associated mitigation plans
- Ensure that the company, its contractors, and vendors are prepared for FDA and Health Authority inspections and host these inspections
- Leads escalations related to External Quality activities for critical issues.
- Supports the inspection readiness program in regards to CROs, CMOs, contract Laboratories, critical starting materials, and suppliers and coordinates responses needed for External Quality topics.
- This role will be located at our San Francisco office and / or up to a 50% remote position (for discussion with applicable candidates)

Your Profile

Education and Experience

Essential

- Bachelor's degree, MS, or PhD in Engineering or Sciences and 10-12 years of experience with a minimum of 5-7 years' experience in Quality Operations and/or external Manufacturing management, or equivalent levels of education and / or experience.
- Cell Therapy, Gene Therapy, Biologics, or other aseptic processing experience is preferred.
- Minimum of 5 years of Sr. Management experience with department and budget management responsibilities
- Experience working with US and EU CROs, CMOs, external laboratories, and clinical sites
- Comprehensive knowledge of FDA and EMA regulations and experience in interaction with US and international regulatory agency inspections.
- Experience in hosting FDA and Health Authority inspections
- Experience and success in a dynamic, complex, and fast-paced team environment
- Experience in identifying compliance gaps, writing, evaluating, and closing investigations with strong technical writing experience.
- A good working knowledge of cleanrooms, aseptic technique and hygienic requirements of sterile products
- Experience of equipment, process, method qualification/validation
- Excellent people leader with strong coaching and mentoring skills
- Ability to synthesize data and summarize outcomes to provide recommendations on a compliant path forward.
- A leader who is self-reflective and leads by example and drives the organization's performance with an attitude of continuous improvement by being open to feedback and self-improvement
- Well organized – a natural ability to be organized in how you think, communicate and conduct your work
- English Language skills
- Good working knowledge of Microsoft office programs
- Domestic and international travel might be required (up to 10%)

Desirable

- Experience building a new quality organization from scratch
- A working knowledge of autologous or allogenic cell therapy processes (including manual and automation involved processes)

- Understanding of QC techniques applicable for in process and final release testing of cell therapy processes
- Experience working in or liaison with a Contract Manufacturing Organization
- Experience of tech transfer of processes and/or facility set-up and design
- Experience working in an early-stage biopharma helping to grow and develop process, people, plant, and culture

Personal Attributes

- A credible leader with demonstrated capability to manage people and projects
- Team oriented and growth mindset, fostering a positive environment for colleagues
- Excellent oral and written communication skills, including presentations and successful negotiations with regulatory agencies
- Capable of managing a wide range of tasks with minimal direction and prioritizing tasks accordingly
- Ability to recommend or take pragmatic actions to control risks
- Strong work ethic and desire to contribute to a growth organization
- Strong attention to detail
- Highly self-motivated and able to motivate others

This job description is subject to change at any time.