tknife TRANSFORMING T-CELL THERAPY

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. We are located at BiotechPark Berlin-Buch in the north of Germany's vibrant capital.

To achieve our goals, we are looking for a

Head of Quality Assurance (EU) (F/M/X)

Tasks

As part of T-knife's growing team you will set-up and maintain the T-knife quality management system (QMS).

- developing procedures and policies for T-knife QMS
- implement document control system for GxP documentation
- conduct periodic internal SOP trainings
- promote a quality culture and monitor effectiveness of the QMS

Perform ongoing QA activities to ensure that manufacturing, testing and clinical trial activities comply with GMP, GCLP, GCP, and other regulatory requirements for cellular therapies including:

- change controls
- corrective and preventive actions (CAPA)
- deviation reporting
- complaint and recall handling
- calibration and maintenance
- qualification & validation
- internal audits
- host external audits and inspections
- vendor qualification including external audits as necessary
- archiving of documents

Advise the T-knife Process Development and R&D teams on Quality related issues.

Support Clinical Development in meeting GCP standards.

Keep Senior Management appraised of significant quality related matters or risks that could impact product quality, product release or regulatory compliance.

Your Profile

- Degree in biology, pharmacy, chemistry or similar.
- At least Five (5) years professional experience in a GCP/GMP environment preferably in early phase development and/or manufacturing of individualized therapies or ATMPs.
- At least Three (3) years quality related experience.
- Track record in writing and/or review of GxP documents (SOP's, qualification/ validation reports and batch records).
- Broad knowledge of clinical processes and procedures, electronic documentation systems, and GCP in EU and US.
- Ability to assess risks and recommend pragmatic actions to control them.
- Demonstrates initiative and proactively provides collaborative support to the internal team.
- Ability to plan and organize work in an efficient manner and work well under time constraints.
- Strong communication skills, team spirit and flexibility.
- Fluent in English and German.

We offer

We offer a permanent position (full-time or part-time) in a young, growing and dynamic company in Berlin. The role will be primarily based at our Berlin office, but remote work will be supported.
Our company culture is defined by a start-up mentality with professional execution, team spirit, motivation and personal drive.
Please send us your full application including possible starting dates and your expected compensation using the email subject "Application TKN0018" to

career@t-knife.com

For additional inquiries please contact the HR department via +49-30-9406-3005.

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