F-STAR JOB DESCRIPTION

POSITION:	Associate Director/Director, CMC
DEPARTMENT:	CMC
LOCATION:	Cambridge, UK
ABOUT F-STAR:	At F-star, we are committed to delivering life-changing treatments to cancer patients. We develop mAb², a novel class of disruptive bispecific antibody-based therapy that have the potential to overcome tumour resistance and restore anti-cancer immunity and responsiveness. F-star is a clinical-stage biopharmaceutical company delivering tetravalent bispecific antibodies for a paradigm-shift in cancer therapy. By developing medicines that seek to block tumor immune evasion, the Company's goal is to offer patients greater and more durable benefits than current immuno-oncology treatments. Through its proprietary tetravalent, bispecific antibody (mAb²™) format, F-star's mission is to generate highly differentiated best-in-class drug candidates with monoclonal antibody-like manufacturability. F-star's laboratory team is based in Cambridge-UK with an expanding footprint in the US to support our clinical stage pipeline.

JOB PURPOSE:

Reporting to the VP, CMC, the Associate Director/Director CMC is a proactive, hands-on scientific leader with a strong technical background in late-stage CMC for biologics. They will play a key role in scientific direction setting and technical oversight for outsourced Drug Substance & Drug Product CMC development and manufacture in support of clinical development of multiple F-star mAb^2 clinical programmes, to eventual commercial registration. This role will work closely with VP, CMC as a pivotal member of CMC leadership and across the Organisation including Quality Assurance, Regulatory Affairs, Clinical Operations.

KEY RESPONSIBILITIES:

You'll be responsible for scientific/technical leadership and oversight of outsourced Drug Substance & Drug Product late-stage/commercial CMC development, manufacture, process characterisation & validation in support of multiple F-star mAb^2 clinical development programmes to eventual commercialisation. This will be delivered through your effective leadership of CDMOs and internal resources. You will serve as a subject matter expert across CMC activities and author/reviewer of relevant sections of CMC documentation in support of CTA/INDs and BLA/MAA submissions and represent CMC function on the Core Project Teams, proactively identifying gaps and risks and working with the team to develop mitigation plans.

- Responsible for successful delivery of outsourced Drug Substance and Drug Product late-stage/commercial manufacturing process development, characterisation and validation for several mAb^2 clinical programmes
- Responsible for clinical supply strategies aligned with Clinical Development Plans
- Oversee the development and implementation of stage appropriate analytical methods and stability studies
- Lead and oversee appropriate critical process parameter studies for the drug substance and drug product preparing for registration and validation batches. Responsible for planning, documenting, and overseeing the execution of all relevant PPQ/PPV protocols
- Review and approval of CDMOs GMP documentation, i.e. specifications, protocols and batch records
- Serve as a subject matter expert and author and/or review relevant sections of CMC documentation in support of regulatory submissions, amendments, and scientific briefing documents

- Maintain in-depth knowledge of manufacturing processes, and quality controls following regulatory guidance and QbD principles in accordance with the cGMP requirements to ensure on-time delivery of the clinical materials
- Establish and maintain CMC budget for assigned projects

PERSON SPECIFICATION:

- Proven track-record of leading late-stage/commercial CMC development for monoclonal antibodies or related therapeutic proteins, process validation, and manufacturing in support of marketing applications and commercialisation
- Experience in clinical and commercial phase biotech environment would be advantageous
- Abreast of cGMP and related regulatory guidelines governing the manufacture of biologics in the UK, EU & USA is desired
- Experience as the primary author of relevant sections of BLAs or MAAs
- Strategic thinking, solution-finding, and agility as evidenced by flexibility, adaptability to change, curiosity, and ability to lead and drive change
- Excellent verbal and written communication skills both through face to face and remote interactions
- Ability to effectively work independently in a team environment and substantial experience with managing external CDMOs to meet timelines within the approved budgets
- Recognises the importance of developing and guiding others and encourages a collaborative approach to learning
- Enjoys working under pressure and meeting deadlines

What F-star can offer you	We get things done, we keep things simple and we're driven by the science. We're ambitious so we work hard to create an environment where we can take smart risks. We want to be innovative so encourage debate and collaboration to challenge the usual way of doing things. We love our celebrations, team work and perks, which make F-star a fun and diverse place to work. And most of all, everyone has the opportunity to make a difference. Benefits: • Pension (8% Employer contribution) • Equity Incentives • Private Medical Insurance • Health cash plan • Life assurance • 25 days holiday, plus the option to buy 5 days. • Travel insurance • Enhanced Maternity, Paternity, Adoption pay • Agile working opportunities