Director CMC Analytical

The Company

TargED Biopharmaceuticals is a clinical-stage biotech founded in 2020. In June 2026 we closed a €40.4 million Series A2 round, backed by a strong investor syndicate including BioGeneration Ventures and Andera Partners, and we are supported by the EIC Accelerator. We are a small, senior team where decisions are made quickly, and every function has a direct line to the program.

TGD001 is a first-in-class antibody-enzyme fusion protein: an anti-VWF VHH fused to a urokinase catalytic domain, designed to dissolve clots of any size or composition while limiting the systemic bleeding risk of today's thrombolytics. After positive Phase 1 results, it is entering Phase 1/2 studies in acute ischemic stroke and thrombotic microangiopathies, including iTTP.

The Opportunity

As Director CMC Analytical, you will own analytical development, quality control and the analytical control strategy for TGD001 DS and DP, from the current clinical stage through scale-up and toward latestage and commercial readiness. You will report to the VP CMC and be the company's analytical lead, internally and in support of regulatory interactions.

Key Responsibilities

- Define and lead the phase-appropriate analytical control strategy for a complex fusion protein, applying QbD principles throughout development.
- Lead method development, qualification, validation and transfer, including potency assays that capture both VWF binding and enzymatic activity.
- Direct characterization, release and stability programs, trend the data, and translate it into specifications, shelf-life and comparability decisions.
- Manage CDMO testing partners as an extension of your own team.
- Author the analytical sections of IMPDs, INDs and briefing packages, and contribute to regulatory interactions with EMA, FDA and other relevant regulatory authorities.
- Ensure GMP compliance and inspection readiness across internal and CDMO analytical activities.
- Lead investigations and root cause analysis and introduce new analytical technologies where they help the program.
- Work closely with Manufacturing, Supply, Quality, Regulatory, Clinical and R&D.

Qualifications and skills

TargED expects its Director CMC Analytical to have:

- PhD, MSc or equivalent in analytical chemistry, biochemistry, pharmaceutical sciences or a related field.
- 10+ years in analytical development for biologics, including leadership of analytical programs.
- Proven late-stage development experience.
- Demonstrated experience applying QbD principles to analytical development and control strategy.
- Hands-on depth in method development and validation for DS and DP, and confident interpretation of release and stability data.
- Expertise in product and process characterization and validation.
- A track record of managing CDMOs effectively.
- Working fluency in ICH, GMP, EMA, FDA and other relevant regulatory expectations; experience writing protocols, reports and regulatory submission content.
- A strong communicator who is well organized, detail-oriented and scientifically curious.
- An entrepreneurial, grounded approach founded in a sense of personal ownership.

Good to have: launch or commercial experience, BLA/MAA experience, and work on fusion proteins, enzymes or other multi-domain biologics.

What can you expect from us?

- Ownership of the analytical strategy for a first-in-class asset at a value-defining stage.
- A direct voice in a small senior team, reporting to the VP CMC.
- Equity participation, to share in the value you help create.
- Based in Utrecht, with the option of hybrid working.

Contact / applications

For applications (motivation and CV) and/or more information please contact:

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No unsolicited services or offers please.