100 High Street, Floor 28, Boston, MA 02210

Position Title:	Director, Process Development
Department:	Pharm Sci & Tech Ops (PSTO)
Hiring Manager:	Head of PSTO
Date Opened:	March 2021

We are a team of experts from multiple disciplines who have come together driven to bring hope with life-changing therapies to patients and their families.

Position Overview:

We are currently seeking a driven, thoughtful leader in the Drug Substance area of expertise. The successful candidate will provide strategic leadership for the operational aspects of the clinical drug substance manufacturing so that a full continuum of services exists to respond to the organizational development needs.

Responsibilities:

- Proven experience in upstream and downstream biologics manufacturing and process validation.
- Experience in management of out-sourced manufacturing/development activities.
- Proven tech transfer and scale-up experience, from development lab to cGMP manufacturing.
- Demonstrated ability to function in a collaborative/team-oriented CMC environment.
- Experience in authoring IND/BLA/MAA and responding to health authority information requests.
- Ability to influence others without direct authority.
- Ability to communicate and connect with all levels of the organization
- Strong project leadership and resource management skills.
- Contract management experience
- Strong background in cGMP, cGLP, and ICH requirements.
- Demonstrated skills in project management and handling multiple projects simultaneously.
- Good verbal and written communication skills.
- Direct all activities of the CMO-based clinical manufacturing of large molecules including but not limited to monoclonal antibodies, fusion proteins, bi-specifics, antibody-drug conjugates and other biologics from early to late stage tech-transfer and clinical manufacturing.
- Oversee and manage process validation studies of molecules
- Manage outsourced manufacturing activities at CMOs.
- Lead and manage external collaborations, ensuring close partnership through scientific and strategic understanding, and attention to partner priorities, to maximize integration and synergy between Catabasis and partner.
- Identify, contract and transfer technology to CMOs appropriate for scale-up and GMP implementation for clinical manufacturing.
- Exercise independent judgment to apply strategy for biologics clinical manufacturing and implementation to enable successful regulatory filings.

- Ensure suitable quality, optimal economics, and adequate supply chain security for biologics clinical products.
- Participate in Project and CMC development teams, in leadership and/or member roles, as required.
- Assembles and submits relevant manufacturing facility and process information to the Regulatory Affairs CMC function for the development of CMC section of NDA.
- Participates on due diligence teams and provide evaluations as required.
- Identify strategic and operational issues, develop proposals, outline solutions, and negotiate time commitments and resources.

Qualifications:

- Ph.D. in biochemical engineering, chemical engineering, biochemistry, or appropriate technical discipline with 10+ years industrial bioprocess development/scale-up and manufacturing experience, including mammalian cell culture and associated downstream unit operations.
- MS with minimum of 15 years relevant industrial experience or BS with minimum of 20 years relevant industrial experience may be considered.
- Minimum of 5 years direct management experience is required within a matrixed organization