Director/Senior Director of Later Stage Process Development CMC

Synthorx is a biotechnology company using a novel synthetic biology platform for the discovery and development of transformational protein therapeutics. We are hiring a driven, resourceful experienced (Sr) Director of Late Stage Process Development CMC to join our high-energy team and lead multiple projects focused on the for immuno-oncology and autoimmune disease indications. The successful candidate will report directly to the Vice President of Chemistry, Manufacturing and Controls (CMC), have a strong background and proven track record in all activities encompassing oversight of bioprocess development, transfer, characterization/validation and support of BLA-enabling activities. We are seeking a scientific leader deeply familiar with biologic drug substance development and manufacturing aligned with requirement for late-stage clinical and commercial products: a self-starting, highly independent and collaborative individual, able to operate at high pace, to meet aggressive timelines.

Key responsibilities

- Accountable for the application of our Extended Genetic Alphabet technology platform to the development and characterization of novel biologic clinical candidates, in coordination with project leaders and our internal Research, Platform Development, Early Stage Protein Sciences, Quality, Regulatory, Pharmacology and CMC teams. With the majority of the CMC activities conducted at third-party organizations, this candidate should have extensive experience partnering, leading and overseeing work performed at external CDMOs and CROs.
- Lead interactions with internal experts, and external consultants and key opinion leaders, to identify traditional and non-traditional strategies for developing, manufacturing qualifying late-stage bioprocesses to deliver new classes of proteins and peptides inherent with our platform.
- Establish and manage best practices for data integrity and reporting compliance.
- Review scope and Statements of Work from Late Stage CDMOs
- Establish and oversee execution of strategy to develop commercial optimized processes at CDMO, delivering robust and cost-effective (low COGs) process from thaw through bulk drub substance. Subject matter expertise in microbial fermentation a plus.
- Direct efforts to conduct full process characterization/validation (PC/PV) using strategy tools from QbD including risk-based DOE tools establishing identification of Critical Process Parameters (CPPs) prior to conducting Process Performance Qualification (PPQ) runs
- Accountable for authoring CMC sections for Synthorx BLA and supporting Pre-Approval Inspection (PAI)
- Build internal capabilities to perform critical PCPV in coming years Contribute to the preparation of corporate, departmental and project goals as well as CMC budget.
- Recruit and develop talent for Late-Stage Process Development group and the entire CMC organization

Required qualifications

- PhD in chemical engineering, organic chemistry or other biochemistry sciences related discipline
- Postdoctoral experience in any of the areas mentioned above is a plus.
- At least 10 years at a biotechnology or pharmaceutical company, working in, bioprocess development, and manufacturing (GMP and non-GMP) with escalating roles of responsibility, including team leadership and people management. Subject Matter Expertise in microbial bioprocesses a strong plus.
- Experience and knowledge with biologic drug classes relevant to immune-oncology and autoimmune diseases, particularly biologics and adoptive cell therapies considered a plus
- Understanding of IND and BLA-enabling CMC activities, including process development and manufacturing.
- Deep familiarity with strategies and tools used in late-stage process development including: Phase 3 development, lock and scale up to commercial-scale; QbD tools of Risk Assessment, PC/PV using single and multivariate DoE studies to define process design space; linking CPPs to Critical Quality Attributes(CQAs); key contributions to Validation Master Plan; and planning and oversight of PPQ runs for BLA submission.
- Strong familiarity with cGMPs, GLPs, GDPs and ICH guidelines
- Hands-on experience with the preparation of documents and regulatory sections supporting IND and BLA submissions.
- Involvement in product (PAI) is a plus
- Strong Leadership experience on internal teams and while working with external CDMOs and CROs.
- Ability to work in a team environment and seamlessly coordinate activities across our internal research and development teams, senior management, CRO/CDMOs, consultants, and regulatory experts.
- Managerial experience and strong communication skills.