Director/Senior Director of Analytical and Formulation Development

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 Head of Analytical and Formulation Development 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 analytical method development, transfer, qualification and testing in support of IND-enabling activities. We are seeking a scientific leader deeply familiar with biologic drug substance and drug product testing, characterization and stability: 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, Protein Sciences, Pharmacology and CMC teams. With much of the CMC activities conducted at third-party organizations, this candidate should have extensive experience partnering, leading and overseeing work performed at external CROs and CDMOs
- Lead interactions with internal experts, and external consultants and key opinion leaders, to identify traditional and non-traditional strategies for analytically characterizing new classes of proteins and peptides inherent with our platform.
- Establish and manage best practices for data integrity and reporting compliance.
- Contribute to the preparation of annual corporate, departmental and project-related goals as well as CMC budget.
- Recruit and develop talent for Analytical and Formulation Development group and the entire CMC organization

Required qualifications

- PhD in chemical engineering, organic chemistry or other biochemistry sciences related discipline, with a strong focus in protein chemistry and analytical methods.
- Postdoctoral experience in any of the areas mentioned above is a plus.
- At least 10 years at a biotechnology or pharmaceutical company, working in analytical and or formulation development with escalating roles of responsibility, including team leadership and people management.
- 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-enabling CMC activities, including process development and manufacturing.
- Strong familiarity with cGMPs, GLPs, GDPs and ICH guidelines
- Hands-on experience with the preparation of documents and regulatory sections supporting IND submissions. Experience in filing BLAs considered a plus.
- Experience working with CROs and CMOs, including technology transfer. Specific experience overseeing analytical method development, qualification/validation, testing and report preparation.

- 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.