Job Description – Associate Director of Late-Stage Analytics and Bioassay Development

Synthorx is a biotechnology company using a novel synthetic biology platform for the discovery and development of transformational protein therapeutics. Using expanded Genetic Alphabet to drive the site-specific incorporation of non-natural amino acids, Synthorx creates therapeutic proteins capable of re-programming receptor interactions leading to potentially effective treatment of diseases. We are hiring a driven, resourceful, and collaborative Associate Director of Late-Stage Analytical and Bioassay Development to join our high-energy team and support biopharmaceutical development. The successful candidate will report to the Sr. Director of CMC Analytical & Formulation Development. He/She will lead the development of cell-based bioassay, immunoassay and biochemical assays for cytokines to support clinical development and regulatory filings. He/She will also have responsibility developing Late-Stage analytical strategies and overseeing their execution. We are seeking a highly motivated and independent individual who can operate at a fast pace, adjust priorities, and manage aggressive timelines.

Key Responsibilities

- Develop, optimize and validate of MOA-reflective potency assay(s) suitable for drug product release and stability testing
- Lead interactions with internal experts, external consultants and key opinion leaders, to identify traditional and non-traditional strategies for characterizing new classes of proteins and peptides inherent with our platform
- Support process development, qualification and comparability studies in a late clinical stage products
- Lead tech transfer of methods to QC labs at CROs or CMOs
- Support regulatory filings including INDs and BLAs
- Edit, review and approve transfer and qualification or validation protocols and reports
- Lead efforts to define product characterization and comparability strategies bridging from early stage to late stage.
- Establish specification for late-clincal and commercial products
- Collaborate with Sr. Director of Late-Stage Process Development to link Critical Process Parameters to Critical Quality Attributes.
- Recruit and develop talent for the assay development group and the entire CMC organization
- Collaborate with other internal bioassay and Early-Stage Analytical groups and provide support to collaborating functional groups as needed
- Enforce Synthorx lab safety policies and best practices at all times

Required Qualifications

- A minimum of a Bachelor's degree in a biochemistry, molecular biology or relevant discipline with at least 12 years of pharmaceutical or related industry experience or a Master's degree with at least 10 years of pharmaceutical or related industry experience or a PhD with 8 years of pharmaceutical or related industry experience

- Broad knowledge and hands-on experience with various biological methods, e.g. SPR, FACS, ELISA, MSD, plate reader, etc.
- Experience with method development and/or supervision of method development in cell-based bioassays, immunoassays and binding assays
- Experience of late-stage assay development, qualification, and validation in GxP environment.
- Experience in setting product specification and assay validation acceptance criteria with statistical analysis
- Strong familiarity with cGMPs, GLPs, GDPs and ICH guidelines
- People management and collaboration with CROs and CMOs
- Attention to detail and exceptional organizational skills
- Ability to work in a team environment and seamlessly coordinate activities across internal teams.
- Proactively plan and manage priority and timelines
- Excellent oral and written communication skills