Job Description – (Assoc.) Director of CMC Supply Chain

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 (Assoc) Director of CMC Supply Chain to join our high-energy team and support biopharmaceutical development. The successful candidate will report directly to the VP of CMC. He/She will ensure the supply of critical regents necessary for the Synthorx platform as well as support distribution of Drug Substance to Fill and Finish operations and subsequently support distribution of filled Drug Product Labeling and packaging. We are seeking a highly motivated and independent individual who can operate at a fast pace, adjust priorities, and manage aggressive timelines.

Key Responsibilities

- Establish and grow the network of manufactures supplying critical, platform specific reagents to Synthorx and Synthorx Contract Development and Manufacturing Organizations (CDMO) to ensure timely supply of pre-clincal and clinical products
- Applying appropriate cost and risk-based strategies, maintain repository of critical reagents and MCB/WCB under GMP storage conditions
- Collaborate with Synthorx Quality to ensure current compliance qualifications of all raw material suppliers as well as DS and DP CDMOs by establishing timely audit plan. Ensure appropriate Quality Agreements are in-place and maintained with all vendors and CDMOs.
- Build and maintain model for Cost of Goods (CoGs) calculatoins and establish scale-up strategies to continually reduce COGs moving toward commercial production
- Collaborate as point contact with Synthorx's DS and DP CDMO to maintain and update overall Bil of Materials (BoMs) for GMP production
- Collaborate with Synthorx Contracts and Legal departments to establish new Master Supply Agreements (MSAs) with all verndors and CDMOs

Required Qualifications

- A minimum of a Bachelor's degree in a biochemistry, business or relavent 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
- Project Management skills to proactively plan and manage priority and timelines
- Strong working knowledge of international shipping requirements to Europe and Asia
- Quality requirements for phase appropriate GMP DS and DP manufacturing
- Familiarity with cGMPs, GLPs, GDPs and ICH guidelines relating to Raw Material and DS and DP supply

- Strong Communication and collaboration skils with CROs and CMOs
- Attention to detail and exceptional organizational skills
- Ability to work in a team environment and seamlessly coordinate activities across internal and external teams.
- Excellent computer and written communication skills