


Synageva BioPharma Corp.

JOB DESCRIPTION

JOB TITLE	Director/Senior Director of Analytical Development
REPORTING RELATIONSHIP	Vice President of Regulatory Affairs and Quality
DATE AVAILABLE	ASAP
LOCATION	Corporate Office, Lexington, MA
RESPONSIBILITIES	<p>The Director/Sr. Director of Analytical Development will be responsible for defining the strategy and assuring the development, validation, and implementation of analytical methods used in the testing of complex glycoprotein products under development. The candidate for this position will interact closely with other scientists and contract research organizations and will play an integral role on multidisciplinary teams that provide support for product and process development, manufacturing and quality functions. The leadership and strategy provided by the candidate will be critical to the assurance of successful product development and global regulatory approvals.</p> <p>The successful candidate will be responsible for achieving the following objectives:</p> <ul style="list-style-type: none">• Development and qualification / validation of analytical methods to support in-process, release, characterization, and stability testing of complex glycoprotein biotechnology products.• Oversight and development of robust procedures for all aspects of analytical testing services and internal laboratory operations as applicable, including management of contract laboratories, sample handling, data generation, verification and interpretation, laboratory and out-of-specification investigations, instrument qualification, operation, and troubleshooting, and all supporting documentation for such activities.• Assess critical analytical resource needs and costs and define strategy for outsourced analytical services versus internal capabilities and infrastructure associated with release, stability, and comparability testing• Assurance of GMP-compliant testing services provided by CROs and planning for migration to compliant internal laboratory environment to include an effective laboratory information management system. Provide functional support for audits and regulatory inspections.• Develop, implement and monitor progress against the company's strategic development plans,• Update and recommend to company's senior management with regard to the status of objectives, projects and goals, particularly as they relate to cross-functional business objectives• Work closely with regulatory staff to assure development of submissions and ongoing compliance with those submissions and regulatory

	<p>commitments</p> <ul style="list-style-type: none"> • Assure the development and review of high quality technical reports required for method development, validation, stability, and comparability efforts • Maintain current state of the art knowledge and evaluation of emerging technologies for analysis of recombinant glycoproteins, with emphasis on support of robust comparability exercises and rigorous characterization of products in development. • Assure that the analytical function is consistent or compliant with all applicable quality, regulatory, HSE, GLP and GMP requirements.
<p>REQUIREMENTS QUALIFICATIONS</p>	<ul style="list-style-type: none"> ▪ PhD + 8-10 years industry experience in analytical, biophysical, biochemistry, molecular/cell biology, or related field (with at least two separate organizations) ▪ 5+ years of supervisory and/or management experience. ▪ Experience with or knowledge of one or more of the following, as appropriate: separation sciences, immunochemistry, glycan analysis, biophysical/ biochemical characterization and bioanalytical sciences. ▪ Candidate must have experience with analytical method development & optimization for recombinant glycoproteins. Industry experience with these activities as part of a technical role in the support of approved commercial products is strongly preferred. ▪ Understanding of worldwide requirements of cGMP and quality systems for commercial and clinical products ▪ Excellent verbal and written communication skills, detail-oriented personality, and ability to work productively in an interdisciplinary team environment. ▪ Ability to work successfully with contract manufacturing and research organizations ▪ Experience interacting with regulatory health authorities at pre- and post-approval inspections ▪ Ability to contribute to quality and compliance decisions or to seek expert advice if necessary on a wide area of topics ▪ Commitment to operational excellence
<p>NOTES</p>	<p>Synageva BioPharma is a publicly held biopharmaceutical company with headquarters, research and development facilities in Lexington, MA, and research and production facilities in Athens, GA. Synageva was formed to concentrate on novel orphan treatments for rare diseases. Our lead program, SBC-102, an enzyme replacement therapy for LAL Deficiency, is in clinical development and has been granted orphan designation by the FDA. LAL Deficiency is a rare, serious and devastating disease that leads to significant morbidity and mortality. Synageva has four additional orphan products in development. To ensure that these therapeutic candidates reach patients in need, Synageva has recruited a team with a proven record of discovery, development and commercial experience within rare diseases.</p> <p>Our work is based on creating value for patients and their healthcare providers,</p>



our shareholders and our employees. Our success brings new treatments to patients and providers. We are building a sustainable business and value for our shareholders because good medicine is good business. Our culture attracts and retains principle-minded individuals of integrity, drive, energy and passion.