

# Synageva BioPharma Corp.

## JOB DESCRIPTION

JOB TITLE	Director/Senior Director of Process Sciences
REPORTING RELATIONSHIP	Vice President of Manufacturing and Technical Operations
DATE AVAILABLE	Open
LOCATION	Lexington, MA
RESPONSIBILITIES	<p>The Director/Sr. Director of Process Sciences will be responsible for defining the strategy and assuring the development, validation, and implementation of biologics manufacturing processes. The candidate for this position will interact closely with other scientists and will play an integral role on multidisciplinary teams that provide support for clinical and non-clinical manufacturing, commercial planning, 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"><li>• Develop and implement robust and scalable manufacturing processes (complex glycoprotein biotechnology products).</li><li>• Develop and oversee a newly formed process sciences function, including: management of external contract development organizations, internal development, process engineering</li><li>• Support manufacturing investigations and regulatory submissions.</li><li>• Manage a multidisciplinary process science team, resources and budget.</li><li>• Develop and implement a development lab capable of meeting manufacturing process objectives.</li><li>• Drive IP manufacturing opportunities</li><li>• Develop, implement and monitor progress against the company's strategic development plans.</li><li>• 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.</li><li>• Work closely with regulatory staff to assure development of submissions and ongoing compliance with those submissions and regulatory commitments.</li><li>• Assure the development and review of high quality technical reports required for method development, validation, stability, and comparability efforts</li><li>• Stay current on emerging technologies for analysis of recombinant</li></ul>

	<p>glycoproteins, with emphasis on support of robust comparability exercises and rigorous characterization of products in development.</p>
<p>REQUIREMENTS QUALIFICATIONS</p>	<ul style="list-style-type: none"> <li>▪ PhD + 8-10 years' industry experience in analytical, biophysical, biochemistry, molecular/cell biology, chemical engineering or related field.</li> <li>▪ 5+ years' of supervisory and/or management experience.</li> <li>▪ Experience with or knowledge of one or more of the following, as appropriate: separation sciences, process engineering, purification development, chromatography, bio-separation.</li> <li>▪ Knowledge of glycoproteins, enzymes, biophysical/ biochemical characterization and bio-analytical sciences is desirable.</li> <li>▪ Understanding of regulatory requirements in drug product and drug product manufacturing including IND and BLA submissions, process validation, including virus validation preferred.</li> <li>▪ Candidate must have experience with manufacturing process development of glycoproteins in a regulated environment. I</li> <li>▪ Industry experience with these activities as part of a technical role in the support of approved commercial products is strongly preferred.</li> <li>▪ Understanding of worldwide of cGMP and process requirements in early, late-stage and commercial manufacturing is preferred.</li> <li>▪ Excellent verbal and written communication skills, detail-oriented personality, and ability to work productively in an interdisciplinary team environment.</li> <li>▪ Ability to work successfully with contract manufacturing and research organizations</li> <li>▪ Commitment to operational excellence</li> </ul>
<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 entering 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, 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.</p>