

Synageva BioPharma Corp.

JOB DESCRIPTION

JOB TITLE	Process Engineer II (Manufacturing Manager)
REPORTING RELATIONSHIP	This position reports to the VP of Manufacturing and Technical Operations
DATE AVAILABLE	Open
LOCATION	Lexington, MA
RESPONSIBILITIES	<p>Process development scientist with 2-5 years industry experience.</p> <p>Process Engineer, manager manufacturing, is a newly formed position developed to support process development and manufacturing activities. The successful candidate will be responsible for the oversight of manufacturing performed through third parties (CMO), data, trending, technical review production planning and logistics. The candidate will be responsible for strategy, design and execution of experiments in conjunction within the process sciences group. They should be capable of working independently and, within a multi-disciplinary team.</p> <p>The successful candidate will be responsible for:</p> <ul style="list-style-type: none">▪ Providing on-going support of manufacturing operations for clinical manufacturing in a cGMP environment. This individual is expected to be the Engineering / Manufacturing support process expert. This positions major responsibility will include:▪ Support material and process changes and▪ Lead in the scale-up and technology transfer through CMO's▪ Perform fundamental engineering and design functions such as drawings, calculations, equipment and materials selection and preparation of specifications▪ Will work with the Process Development team on the design, execution and reporting of process related experiments and proposed process changes.▪ Understands and employs scientific and engineering practices according to the industry standards.▪ Provides technical input and support to internal customers on issues of manufacturing equipment and/or processes, process changes, test methods, validation, regulatory compliance, failure investigations and creation and implementation of corrective actions.▪ Designs and executes experimental studies and engages in POC and scale-up activities.▪ Candidate provides sound knowledge of process and/or product design principles to affect the engineering, procurement and manufacturing start-up for existing or new products and processes or improvements to existing products and processes.▪ Candidate performs experiments necessary to demonstrate scalability and process improvement opportunities.

	<ul style="list-style-type: none"> ▪ This position identifies areas of need and works independently to determine the project scope, direction, and objectives.
<p>REQUIREMENTS QUALIFICATIONS</p>	<p>Our ideal candidate should have an MS in Chemical Engineering, or Biochemical Engineering with at least 5 years biopharmaceutical experience. The ability to write SOPs and MBR is expected. Demonstrated knowledge of cGMPs is required. Knowledge of protein biochemistry is desired.</p>
<p>NOTES</p>	<p>Synageva BioPharma is a privately 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 Lysosomal Acid Lipase (LAL) Deficiency, a serious and life threatening lysosomal storage disease, 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, 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>