

# Synageva BioPharma Corp.

## JOB DESCRIPTION

JOB TITLE	Quality Assurance Associate
REPORTING RELATIONSHIP	Director, Quality Assurance
DATE AVAILABLE	Open
LOCATION	Athens, GA
RESPONSIBILITIES	<p>This position's primary responsibility will be to support Isis quality systems as they relate to the manufacturing and testing of Drug Substance (DS) and Drug Products (DP) in a current Good Manufacturing Practice (cGMP) environment. Principal duties include, but are not limited to: (1) providing general support for the Environmental Monitoring, Raw Materials, stability and water testing programs, (2) review of documentation and quality records.</p> <ul style="list-style-type: none"> <li>• Collect and process samples for Environmental Monitoring (viable, non-viable, and surface samples) of cGMP manufacturing areas.</li> <li>• Collect and process samples for TOC, conductivity, microbial, and endotoxin testing at the specified ports within the Purified Water system.</li> <li>• Coordinate the required contract testing of water and environmental samples, and manage the receipt of test results. Trend the data on a routine basis and compile annual summary reports. Perform investigations into aberrant test results.</li> <li>• Perform batch record review activities for reagent preparation, intermediate, DS and DP batch records and associated analytical data packages.</li> <li>• Review the analytical data packages associated with stability testing time points for both DS and DP stability studies. Recognize and communicate trends associated with the data over time.</li> <li>• Manage electronic entries into the QMS. Provide follow-up for and track-to-closure all open entries in the system. Prepare reports for Management</li> <li>• Review detailing all Quality System metrics.</li> <li>• Perform the QA/C release function for Raw and Starting Materials, including review of the lot file, completion of release documentation, and issuance of status labels.</li> <li>• Review and approve forms associated with facility and equipment activation, calibration, maintenance, and alarm procedures.</li> <li>• Review Standard Operating Procedures (SOPs), logbooks, and other documentation related to daily QA operations.</li> </ul>
REQUIREMENTS QUALIFICATIONS	<ul style="list-style-type: none"> <li>• Bachelors degree in a relevant discipline (e.g. chemistry, biology, engineering)</li> <li>• Strong computer skills</li> <li>• Effective communication (verbal and written), interpersonal and teamwork skills</li> <li>• Previous Quality Assurance experience a plus</li> <li>• Ability to be productive and successful in an intense work environment</li> </ul>
NOTES	<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 deliver orphan treatments for patients with rare diseases. Our lead program, SBC-102, an enzyme replacement therapy for LAL Deficiency, a serious and life threatening lysosomal</p>

storage disease, is in clinical development and has been granted orphan designation by the FDA. LAL Deficiency is a rare 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.

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.