

**POSITION TITLE:** Quality Assurance Associate

**POSITION DUTIES:**

Spring Point Project is committed to improving the lives of people with Type 1 diabetes by providing a virtually unlimited supply of medical-grade, high-health pigs to serve as safe islet cell donors to people with diabetes. The Quality Assurance Associate performs activities associated with the quality assurance of porcine (swine) islet, encapsulated islet combination products, systems and components thereof. The Quality Assurance Associate assists the Director of Quality to ensure that all products produced at Spring Point Project adhere to Spring Point's Quality Management System, client, vendor, and pertinent, associated quality and regulatory requirements. The specific job duties are the following:

- Responsible for Quality support at Spring Point Project and may include oversight via direct staff management or process/area responsibilities.
- Identify and assess regulatory and quality risk in activities and processes according to regulatory agency rules and guidelines along with Spring Point Project quality practices.
- Assist in management of Quality Management Systems, cGMP training, Master Validation Plan, and Continuous Improvement Program. This includes both large and small scale projects to support compliance and FDA product approval for interstate commerce.
- Write, review, assess and revise Standard Operating Procedures (SOPs) and submit procedural changes as needed.
- Apply working knowledge and experience with all federal and state regulations and requirements and industry standards related to FDA and USDA regulated products.
- Conduct vendor and internal audits and inspections.
- Adhere to and support safety standards, policies, and practices.
- Assist Document Control personnel with document administration functions as needed.
- Other assignments as required.

Travel: Infrequent overnight domestic travel as normal and customary for the position to perform on-site audits of suppliers, as part of a team initially and thereafter, depending on the scale and scope of the audit, approximately 5% of the time.

## **POSITION REQUIREMENTS:**

1. Bachelor's degree in Biology, Chemistry, Microbiology Biochemistry or related scientific field.
2. Two years of experience as a Quality Assurance Analyst, Quality Control Technician or closely related, including:
  - a. QA experience in GMP, GLP and/or ISO regulated environment, conducting audits, documentation generation, review, and continuous improvement.
  - b. Experience with GLP/GMP regulations and practices.
  - c. Experience with IT terminology and application of computer system regulatory practices (e.g. 21 CFR part 11 compliance, data integrity, Excel spreadsheet validation).
3. Quality Certification from the American Society for Quality (ASQ), Six Sigma Yellow Belt Certification, or equivalent.
4. In place a Quality Certification will accept instead 4 years of relevant experience, rather than two, as outlined above.
5. All experience can be gained concurrently
6. Due to the need for extremely high herd health, the position requires meeting strict biosecurity (primarily personal and intimate contact's swine contact/withdrawal time), background, and pre-employment health screening requirements.

**Applicants who are interested in the Position should send a cover letter and resume to:**  
Thomas Spizzo, Executive Director, [tspizzo@springpointproject.org](mailto:tspizzo@springpointproject.org)