



Job Description			
Fill in The Blanks Below			
Position Title:	Staff QA Product Development Engineer	FLSA Classification:	Exempt
Reports To:	Sr. VP Operations – Direct CEO – dotted line	Band:	
Location:	Atlanta, GA	Last Reviewed:	July, 2009

Position Summary (A broad statement that captures the essence and overall purpose, 2-4 sentences.)

Headquartered in Fort Lauderdale, Florida, LifeSync Corporation is a medical device company committed to the development of innovative products that improve clinical outcomes for patients through the use of LifeSync® products and technologies.

LifeSync is currently partnering with Georgia Tech in Atlanta to develop and validate the performance, safety, and effectiveness of our next generation of products. This new research partnership and a strong desire to maintain excellent processes in the continued validation and verification of the performance of the changes made within the sustaining engineering group and created need for the position of **Staff QA Product Development Engineer**.

The **Staff QA Product Development Engineer** will establish and maintain a proactive, leadership role in New Product Development projects specific to the quality discipline. This will involve partnering with the LifeSync R&D Department in successfully launching of our next generation of products and partnering with the Corporate Engineering group to create compliant validations and verification based on the risks associated with the changes made.

Essential Functions: (Core duties that are fundamental for the position to exist. Define purpose, function, result to each duty, frequency, and time spent in brief phrases, not sentences. List duties in order of descending importance. Each statement should include: begin with an action verb in the present tense, activity type/type of work, object reason, i.e. Determines account service problems/issues to minimize loss, or Analyzes project needs and updates weekly, or Maintain subsidiary automated documentation system bi-weekly. List most important functions first.

Represent the Quality group on New Product Development projects by partnering with R&D, Operations Engineering, and Materials resulting in the delivery of on time quality elements including design control planning and execution, validations, verifications, regulatory reviews, protocol development, quality plans, procedures, forms, testing, and due diligence activities.

Make active use of industry standard/best practice quality principles and tools (e.g. SPC, DFMEA, design reviews, cost of quality evaluations, problem solving tools) through application to R&D and Sustaining Engineering projects and development of specific training modules.

Establish strong working relationship and work closely with the early supplier base by assuming the lead role for quality on engineering projects as well as role of instructor/mentor.

Maintain accurate and up to date records and reports on projects and initiatives as assigned.

Secondary Functions: (Describe duties or tasks using the format for essential functions that are necessary to a lesser degree, requiring < 5% of your time spent AND may not be critical.)

- Must be able to work independently and be a self-starter. Must be able to deliver periodic reports that report on the success of the projects underway.

Interactions/Relationships: (Identify key relationships; position title, purpose and frequency of interactions i.e. Attorney, producing correspondence daily; or Project Manager, flowcharting action, weekly; may include external sources.)

- R&D Team in Atlanta
- Operations Engineers in Fort Lauderdale
- Management in Fort Lauderdale
- Quality Department at LifeSync
- Outside suppliers and contractors
- Internal and external consultants
- Customers of our products

Position Specifications: (Identify the minimum qualifications needed; education level or equivalent, minimum years of experience. Use required, essential, preferred or plus for each. Also identify KSAs; knowledge, skills, abilities and competencies, i.e. Knowledge of cost accounting inventory valuation methods required or skilled in using MS project and Visio preferred, analytical skills required.)

A minimum of a Bachelor's degree with major in engineering is required. Mechanical Electrical or Biomedical Engineering is preferred.

Must have minimum 5 years experience in product development in Medical Device, Biologics or Pharmaceuticals.

Must have demonstrated project management skills

ASQ quality engineer accreditation is preferred

Six-sigma Green Belt or Black Belt certification is preferred

Ability to write technical documents, procedures and reports is a must

Ability to read and interpret engineering drawings, electrical/electronic schematics and PCB layout drawings is required

Must be able to travel (up to 25% of time)

Experience in mechanical measuring, fault finding, and statistical analysis

Must be PC literate (Word, Excel, PowerPoint), MS Project

Must have the ability to effectively communicate both in writing and verbally, to all levels of the organization

Physical/Mental/Physical Environment: The work environment characteristics and physical demands described here are representative of those an employee encounters while performing the essential functions of the job. Reasonable accommodations will be made to enable people with disabilities to perform the essential functions. (Requirements of the position as it is typically performed. Consider senses and environment items, i.e. strength, vision, noise, movement, talk, hear, sit, use hands/fingers, reach, bend, equipment heights, odors, hazards, etc.)

Regularly required to stand; walk; talk; sit; use hands to handle objects and feel controls; reach; climb stairs; stoop; crouch; talk; listen; and have vision capabilities that enable reading and viewing a computer screen.

The employee may occasionally lift up to 25 lbs.

Disclaimer: The above statements are intended to describe the general nature and level of work being performed by employees in this position. They are not intended to be construed as an exhaustive list of all responsibilities, duties, and/or skills required of all personnel. The above duties are subject to change and shall not be construed as a promise or contract of employment or of any specific duties.