

## **Sedia Biosciences Corporation**

### **Job Description**

**Job Title:** QA Specialist II  
**Department:** QA  
**Reports To:** QA Manager/Director  
**FLSA Status:** Exempt  
**Prepared By:** Nancy Lime  
**Prepared Date:** 13AUG2020  
**Approved By:** Ron Mink  
**Approved Date:** 20 Aug 2020

#### **Summary:**

Maintains and may implement aspects of the Quality System required to support Sedia's products. Demonstrates independent judgment and discretion in the timely identification, investigation and resolution of events that may or may not impact the quality of products, processes and resources. Administers at least one Quality System. Provides metrics to demonstrate functionality of the Quality System(s) of responsibility on a routine basis to area Managers

#### **Primary Responsibilities:**

- Performs QA activities within the Quality System to maintain and/or ensure compliance to governing documents; performs data entry and moderately complex analysis and assess results in collaboration with more senior Operations personnel.
- Performs record review for compliance to governing documents.
- Performs activities to meet the production schedule and project timelines.
- Other duties as may be assigned by supervisor.

#### **Supervisory Responsibilities:**

- May lead a small team (informally) of scientists and technicians for short term projects.

#### **Essential Functions and Competencies:**

To perform the job successfully, an individual should demonstrate the following competencies:

Analytical:	Collects data; Provides input on workflows and procedures.
Design:	None
Problem Solving:	Gathers information in a timely manner and provides to team assigned to task of problem solving; works in a group problem-solving situation.
Project Management:	None
Technical Skills:	Competent knowledge in functional area of responsibility. Pursues training and development as directed by supervisor. Shares expertise with others.
Customer Service:	Reports customer complaints or concerns. Meets customer commitments.

Interpersonal Skills:	Good interpersonal skills and ability to work with others. Focuses on solving conflict, not blaming. Maintains confidentiality. Listens to others without interrupting. Keeps emotions under control. Remains open to others' ideas and tries new things. Disagrees with respect for others' views and needs, and not out of emotion.
Oral Communication:	Speaks clearly and persuasively in positive or negative situations; listens and gets clarification; responds well to questions; participates in meetings; focused on clear polite respectful communication.
Written Communication:	Writes clearly and informatively. Able to read and interpret written information.
Teamwork:	Supports team responsibilities. Exhibits openness to others' views; Gives and welcomes feedback; Contributes to positive team attitude; Supports everyone's efforts to succeed.
Visionary Leadership:	None
Change Management:	Supports implementation and other plans resulting in change; Supports those affected by change.
Delegation:	May not delegate tasks but may seek cooperative support.
Leadership Skills:	Strives to exhibit confidence in self and inspire confidence in peers; Strives to set a standard of excellent performance for peers and others in the team; Accepts feedback from others; Gives appropriate recognition to others. Displays positive work ethic and commitment to quality.
Managing People:	No formal people management responsibilities. Seeks to elicit cooperation from others using soft skills including encouragement, buy in, collaboration and sharing of credit.
Quality Management:	Committed and supportive of Good Quality Output, and the Company Quality Policy. Looks for ways to improve and promote quality.
Business Acumen:	Shows an awareness of focus on corporate goals.
Cost Consciousness:	Helps implement cost saving measures; Conserves organizational resources.
Diversity:	Demonstrates knowledge of EEO policy; Shows respect and sensitivity for cultural differences; Promotes a harassment-free environment.
Ethics:	Treats people with respect; Keeps commitments; Inspires the trust of others; Works with integrity and ethically; Upholds organizational values.
Organizational Support:	Follows policies and procedures; Supports organizations goals and values; Supports affirmative action and respects diversity.
Strategic Thinking:	None
Judgement:	Displays willingness to make decisions on own work; Generally, displays sound and accurate judgement; Can generally support and explain reasoning for decisions; Seeks input for decisions that aren't clear or more information is needed in decision-making process as needed.
Motivation:	Strives to be self-motivated, seek out tasks without being told to perform in all cases and identifies challenges for self-improvement. Accepts consequences of failures in judgement and strives to learn from them.
Planning/Organizing:	Plans personal work activities; Uses time efficiently.

Professionalism:	Approaches others in a tactful manner. Reacts well under pressure; Treats others with respect and consideration regardless of their status or position; Accepts responsibility for own actions; Follows through on commitments.
Quality of Work:	Demonstrates accuracy and thoroughness; exhibits attention to detail.
Quantity of Work:	Generally, meets productivity standards; Completes work in timely manner; Strives to increase productivity.
Safety & Security:	Observes safety and security procedures; Determines appropriate action using guidelines; Reports potentially unsafe conditions; Uses equipment and materials properly. Ensures that facility security measures are followed, and intellectual property and company confidential information is secured from outside parties.
Adaptability:	Adapts to changes in the work environment; Manages competing demands; Changes approach or method to best fit the situation; Able to deal with frequent change; delays; or unexpected events.
Attendance/Punctuality:	Is consistently at work and on time; Ensures work responsibilities are covered when absent; Advises supervisor of planned absence in advance and notifies office when unexpected absence prevents appearing at work. Arrives at meetings and appointments on time. Displays respect for other people's time.
Dependability:	Follows instructions, responds to management direction; Takes responsibility for own actions; Keeps commitments; Commits to long hours of work when necessary to reach goals; Completes tasks on time or notifies appropriate person with an alternate plan.
Initiative:	Volunteers readily; Willing to undertake self-development activities; Asks for and offers help when needed.
Innovation:	May identify new ideas for projects and products; May generate suggestions for improving work; Suggests ideas and information to others.

## **Qualifications:**

### **Education and/or Experience:**

- B.Sc./M.Sc. in applicable biological science or chemistry with 5+ years' experience.
- Prior experience in medical device or pharma arena preferred; must have prior relevant laboratory experience of at least 2 years
- Relevant hands on experience in specific Quality Assurance roles. Experience working under a quality system such as ISO 13485 or 21 CFR part 820 c GMPs or GLP.
- No supervisory experience required

### **Language Skills:**

Ability to read and interpret technical procedures. Ability to effectively present information and respond to questions from groups of peers and supervisor. Proficient in English.

**Mathematical Skills:** Ability to perform basic math functions (addition, subtraction, multiplication, division) and to apply concepts such as fractions, percentages, ratios, proportions, calculations of means, standard deviations, and coefficient of variances ("CV's") to practical situations. Ability to perform simple unit of measures conversions (incl. metric vs US). Ability to perform simple concentration: volume equivalencies; basic familiarity with significant digits.

**Reasoning Ability:** Ability to define simple problems, collect data, establish facts and draw basic valid conclusions.

**Computer Skills:** Proficient in the use of an Internet Browser(s), Email, Microsoft Word, Microsoft Excel; Adobe Acrobat

**Certificates, Licenses, Registrations:** None

**Other Skills and Abilities:** Displays organization skills including ability to maintain an organized work environment; Good technical skills including knowledge, understanding and experience with ELISA or LFIA type assays specifically is a plus, and with in-vitro diagnostic assays in general highly desired; ability to think logically and carryout troubleshooting of problems is highly desired.

**Other Qualifications:**

- Works well under pressure and under specific time constraints without getting frustrated; works productively under tight deadlines.
- Ability to work with outside vendors, contract manufacturers and service providers

### **Physical Demands:**

While performing the duties of this job, the employee is regularly required to sit and talk or hear. The employee is occasionally required to stand; walk; use hands to finger, handle, or feel and reach with hands and arms. The employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, color vision, depth perception and ability to adjust focus.

**Work Environment:** The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

General Environmental Exposures: May be exposed to wet, humid conditions; dry (<25% RH) conditions; occasionally to extreme cold

Elevation: Occasionally exposed to moderately high places (e.g. ladders up to 16 feet).

Reagent and Chemical Exposure: Occasionally exposed to fumes or airborne particles; irritating, toxic or caustic chemicals.

Mechanical and Electrical Exposure: Occasionally exposed to moving mechanical parts, vibration, and slight risk of electrical shock.

Biohazardous Agent Exposure: Occasionally exposed to human pathogens either live or inactivated, and human body fluid specimens. Training in handling of bloodborne pathogens and appropriate safety equipment provided.