# McGuff Pharmaceuticals, Inc. Senior Quality Assurance Supervisor

**McGuff Family of Companies**

We’re growing and looking to hire a Senior Quality Assurance Supervisor to expand our Quality Assurance Department!

McGuff values its employees as one of our most important resources. We strive for a vibrant, healthy work culture and attain it through good communication, active involvement, and corporate responsibility. We leverage our employees’ expertise and support their professional development for mutual growth.

**About McGuff**

McGuff was established in 1972 and has remained family and veteran owned. The McGuff family of companies consists of three unique entities: McGuff Company, Inc. (MCI) – medical products distribution; McGuff Pharmaceuticals (MPI) – drug manufacturing; McGuff Outsourcing Solutions (MOS) 503 B compounded drug manufacturing. All McGuff companies are registered with the Food and Drug Administration and adhere to strict quality standards.

We are committed to providing our customers with high-quality, fairly priced drug products, while achieving fast delivery and excellent customer service. All employees at McGuff take pride in and work hard to maintain our valued reputation with our customers worldwide.

McGuff Pharmaceuticals operates as a FDA registered commercial sterile drug manufacturer and as a 503B sterile and non-sterile drug manufacturer utilizing two separate facilities in South Santa Ana, California.

**Job Description:**

The Senior Quality Assurance Supervisor will oversee and be responsible for (1) ensuring the Quality Assurance Systems of McGuff Pharmaceuticals are focused on prevention and are proactive, (2) supervising designated QA personnel, (3) authority for the proper documentation and effectiveness of all processes, systems and functional specifications that are used to ensure the release and rejection of all components, drug product containers, closures, in-process materials, packaging materials, labeling, and finished drug products, (4) authority to review control records, stop production activates and recommend improvements to assure that processes conform to established qualified/validated procedures and processes, (5) authority to ensure and verify that manufacturing errors are fully investigated and documented as appropriate, (6) ensuring Quality Assurance systems are developed, implemented, maintained, improved and properly executed to assure safe and effective products as produced by McGuff Pharmaceuticals.

He/she will work closely with a wide range of other employees to ensure that all applicable policies and procedures, state and federal laws and regulations, ISO and cGMP requirements are met.

**Duties include, but are not limited to:**

1. Responsible for Quality Assurance System procedures, activities and personnel.
2. Understanding the Company’s Product’s intended uses.
3. CAPA System administration, coordination and effectiveness.
4. Ensuring all non-conformances are properly identified, documented, resolved and appropriate CAPAs are effectively implemented. Including but not limited to:
	1. Out of Specification conditions (OOS)
	2. Material Review Boards (MRB)
	3. Service/Product complaints
	4. Returned goods
	5. Non-conformance identification and resolution procedures
	6. Deviations
	7. Risk Analysis and Risk Management
	8. Root cause identification and elimination
	9. Change management
	10. Statistical analysis and the reduction of process/product variability
5. Ensuring Quality Assurance Investigations (INV system, SOPs and files) are properly identified, controlled, thoroughly conducted, effective and closed in a timely manner.
6. Ensuring internal audits program is implemented, timely, effective and identified observations are properly communicated, rectified and properly followed-up for final closure.
7. Ensuring that all Quality Assurance systems are properly coordinated, cross references and integrated to ensure continuity of communications, documentation and that CAPA is traced back through the appropriate non-conformance documentation system.
8. Identify opportunities for improvement and champion improvement projects.
9. Participate in, lead and control third party inspections (e.g. FDA, EU, Customer, Board of Pharmacy, etc.).
10. Assist in resolving and implementing responses to and corrective action for all third party inspection reports.
11. Daily supervision of designated Quality System personnel assignments and duties.
12. Assigning work and schedules to designated personnel, as appropriate.
13. Ensuring overall Quality Assurance systems and activities are compliant with world-wide regulatory requirements.
14. Ensuring Quality By Design and product life cycle approaches are practiced throughout the Quality Assurance system.
15. The McGuff Quality Culture is promoted and adopted.
16. Other varied duties as assigned by his/her immediate supervisor.

**Physical Requirements:**

The position requires bending, squatting, climbing, and reaching above shoulder level. In addition, the job will require sitting, standing, walking, handling and manipulating objects (manual dexterity and fine finger movement).

**Qualifications include:**

1. Minimum education: Bachelor of Science degree in related field.
2. Minimum of 7 years relevant industry experience ideally in a Quality Assurance regulated environment.
3. Experience as a department leader.
4. Experience with quality systems. Especially Quality Assurance aspects such as non-conformance identification and CAPA systems in pharmaceutical manufacturing firms.
5. Knowledge of FDA cGMP requirements.
6. Knowledge of ISO 9000 requirements.
7. Knowledge of QA laboratory operations, methods and controls.
8. Computer literate and familiar with computerized manufacturing, e-batch records, inventory monitoring, tracking and control systems.
9. Experience in or exposure to 503B Outsourcing Facility quality, regulations, operations and processes.
10. Demonstrated critical thinking skills and proven ability in Root Cause Analysis along with exceptional technical writing skills.

**Expectations:**

1. Responsible for the clarity, proper implementation and effectiveness of all assigned Quality Assurance systems and presenting such to regulatory authorities as needed.
2. Appropriate professional demeanor.
3. Ability to work with others.
4. Excellent communication skills.
5. Work with all McGuff employees to foster and promote quality throughout the entire organization.
6. Hold true that the quality of the work you and your team provide becomes the organization’s standard.

This is a full-time, on-site role located at 4040 W. Carriage Drive, Santa Ana, CA. If you are interested in this opportunity, please apply online with your resume and cover letter. We offer a competitive salary and benefits package, as well as a dynamic and supportive work culture. We are an equal opportunity employer and value diversity and inclusion. We hope to hear from you