Tower Laboratories, Ltd.

QUALITY ASSURANCE (QA) MANAGER – Pharmaceutical Mfg.

Montague, MI

Tower Laboratories is a leading provider of effervescent products in the United States. We specialize in the application of effervescence as a product delivery system. We develop and manufacture over-the-counter medications, prescription pharmaceuticals, dietary supplements, personal care, beverage and household products. We are expanding our product base and currently have several new and interesting products in the development stages as well as several beginning production right now. Please visit our website to learn more about us at **www.towerlabs.com.**

POSITION SUMMARY:

The QA Manager, along with the QC Manager, work closely with the VP of Quality to ensure the manufacture and timely release of a quality product which meets and/or exceeds all specifications, is compliant with FDA and other regulatory agencies, and is fully integrated with Tower Laboratories' business objectives.

This position has the responsibility to lead, coach and provide direction to Quality professionals in our Montague, MI facility.

ESSENTIAL FUNCTIONS:

1. Manage activities and workflow in the QA department on both a strategic and day to day level; assess needs and propose solutions accordingly to achieve business and operational objectives.
2. Manage, coach and provide direction to QA personnel; assess and leverage strengths and provide training and/or developmental opportunities as appropriate.
3. Develop and track metrics to evaluate the effectiveness of the quality system. This includes formal management review and development and tracking of corrective action plans and continuous improvement initiatives.
4. Authorize Release of final product.
5. Evaluate quality events using a risk based approach; lead investigations of product quality issues, as appropriate, and write investigation reports.
6. Monitor/track CAPA's and partner with team members to ensure effectiveness and on time completion.
7. Partner with operational colleagues to ensure compliance with all SOPs.
8. Lead internal and external audit activities. Respond to audit reports including FDA 483's, etc. Work with Compliance Manager to lead corrective and preventative action activities for audit responses.
9. Communicate with Customers or Sales Department, as needed, on quality matters including release status, registration documentation, complaint handling, etc.
10. Review product specifications, participate in establishment of validation /qualification requirements (including protocol review), review APRs.
11. Serve as role model for creation of high quality culture.

QUALIFICATIONS:

- Min. 7 years' experience in management of Quality operations in a cGMP environment.
- Comprehensive knowledge of FDA regulations pertaining to manufacture of drugs, dietary supplements and/or food.
- Proven track record of partnering with production management in terms of championing quality principles and facilitating risk-based resolutions to quality events.
- Strong leadership and managerial skills; experience building effective working teams.
- Strong working knowledge of Quality release activities including material and component approval and batch record review.
- Strong analytical skills; demonstrated ability to solve problems
- Ability to function independently; highly motivated self starter
- Commitment to Quality; possess a continuous improvement mentality
- High level of integrity and ethics
- Ability to integrate strategic objectives into daily operational functions (seeing the "big picture")

This medium sized company is privately owned and maintains a friendly, dynamic, positive working environment. We offer a competitive insurance benefit package and 401(k) with company match. Tower Laboratories is a Socially Responsible Employer and a great place to work!

Qualified candidates, please submit resume and letter of introduction to start the conversation today: hr@towerlabs.com