Quality Assurance / Quality Control Manager
Job Description

We're a family owned and operated company, which has been manufacturing pharmaceuticals since 1966. Join our 17 person team in a vital role. Help us market quality products designed to help chronic wounds heal. Visit www.dakins.net for more company and product information. Please contact us via email, at suchindas@dakins.net, or call 317-849-4210, if this sounds like it might be a good fit with your goals. This could be either a full or part-time position, but you must have a BS degree.

Job Description:
Formulate and refine the company’s current Quality System. Plan and direct the Quality Assurance / Control program, designed to insure continuous production of products consistent with established standards. Plan, promote and organize training programs related to the company’s Quality System.

Education and Experience:
BS Degree in chemistry or biology, with 1 – 2 years experience in Quality Assurance in the pharmaceutical or medical device industry. Must have a working knowledge of GMP requirements.

Job Duties:
- Audit Manufacturing, Packaging and Lab paperwork for accuracy and completeness.
- Monitor the QA Technician’s work, specifically making sure stability tests are completed on time.
- Record test results in the computer.
- Analyze the stability test results, and take follow up action based on those results. (For example, schedule any tests needed in addition to those normally scheduled.)
- Make sure employees understand and comply with SOP’s.
- Train employees with regard to following the company’s SOP’s and its Quality System.
- Evaluate product and process deviations and retrain staff as needed.

- Audit various departments, as assigned by the Director of Regulatory Affairs, on a yearly basis. Write up the audits and present them to the Management team, including suggested improvements and timelines for completion.
- Review product labels and recommend appropriate changes as needed, or as determined by new evidence or regulations.
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- Work with the Operations Manager to communicate changes in manufacturing, packaging, labeling, or other processes or procedures.
- Perform a 2nd person in-process review of lab procedures performed by the Chemist.
- Have a working knowledge of all cGMP rules and regulations, and develop a system of effectively implementing them, according to written guidelines.
- Have a working knowledge of ICH guidelines and of laboratory regulatory guidelines.
- Participate in Quality Meetings, presenting ideas to management for improvement.