Senior Vice President of Quality Assurance

Duties and Responsibilities:

- Manage the QA /QC department, including staffing, development and training of personnel.
- Provide regulatory affairs oversight and quality leadership for product development, operations, and commercial activities.
- Develop and implement regulatory strategies for approvals of new products.
- Lead multi-disciplinary and multi-cultural teams to support ongoing improvement of GMP standards and compliance.
- Ensure compliance with regulations in all applicable markets (including US, EU, Canada) and any new markets, as needed.
- Oversight of labeling and promotional activities in accordance with approved indications and claims.
- Provide regulatory and business oversight of laboratory testing and procedures relating to OTC drug product approvals.
- Establish, maintain, manage and continuously improve the Quality Management System in compliance with FDA and other applicable regulations and standards.
- Liaison with the FDA, third party auditors, customer auditors and other regulatory inspections.
- Participate in the Management Review Process, regulatory strategies, product submissions, licenses and registrations, including 510(k).
- Any other high-level management tasks as needed.
- Develop and improve Quality Assurance Systems.
- Reports directly to the CEO.
- Ability to perform gap analysis and implement immediate improvements.

Education & Certifications:

B.S. Engineering, Science or another technical field. Advanced Degree preferred but not required, with appropriate experience**.**

Work Experience:

- Experience in OTC Drug, regulatory affairs and quality assurance.
- Large and small company experience with need to have diverse skill set.
- Industry experience is a requirement, governmental experience not required.
- Minimum 10 years pharmaceutical or medical device experience in a leadership position.

Knowledge, Skills & Abilities:

- In depth knowledge of regulations and quality systems, in particular CFR parts 210, 211 and 800.
- Leadership, management and communication skills (oral and written).
- Collaborative and cooperative team player with strong emphasis on leadership.

About OraLabs, Inc

OraLabs is an FDA registered OTC drug and cosmetic manufacture. Our markets cover contract manufacturing for many household brand names, private label store brands and our own brands. For more information visit www.oralabs.com**.** OraLabs, Inc. 18685 East Plaza Dr., Parker Colorado 80134

To Apply:

Qualified candidates may apply by sending their resume and cover letter to rpeterson@oralabs.com.
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