

Protecting the Vulnerable™



POSITION SPECIFICATIONS

Director – Quality Assurance and Regulatory Affairs

14-APR-2020



ABOUT OUR COMPANY

Mesa Laboratories, Inc. (Mesa) is a global technology innovator committed to solving some of the most critical quality control and analytical challenges in the pharmaceutical, healthcare, industrial safety, environmental, food and beverage industries. Mesa offers products and services through four divisions (Sterilization and Disinfection Control, Instruments, Cold Chain Monitoring and Biopharmaceutical Development), which help our customers ensure product integrity, increase patient and worker safety, and improve quality of life.

Today, each of Mesa's products and services play a role in ensuring the safety and efficacy of the products we use every day. No matter if it's the environment, products or people, Mesa is committed to Protecting the Vulnerable™.

Founded in 1982, Mesa went public in 1984. After 10 years of more than 15% growth per year, the company now has revenue exceeding \$100M and a market cap of approximately \$1.1B. Our growth is attributed to the 350+ dedicated employees who follow our customer-focused, lean-based value system, called *The Mesa Way!*. The Mesa Way! is based on four pillars that drive our work every day:

Measure what Matters: We take the customer's perspective, our "True North", both to measure what matters most to customers and to set absolute standards for performance. We manage to leading indicators, which drive us to proactively avoid problems.

Empower Teams: We move decision making as close to the customer as possible and provide the structure and real time communication forum to align the whole organization behind surpassing customer expectations.

Steadily Improve: We leverage a common and proven set of lean-based tools to prioritize our biggest opportunities, address those opportunities at root cause, and quickly implement change.

Always Learn: We ensure that improvements are sustained, enabling us to raise performance expectations and repeat the cycle of improvement. Equally, this cycle strengthens the Mesa team by providing endless learning opportunities for our employees and helps us to become an employer of choice in our communities.

Position: **DIRECTOR – QUALITY ASSURANCE AND REGULATORY AFFAIRS**

Posting expires **28-FEB-2020**.

Posting Expiration: Screening of resumes will begin **immediately**; resumes accepted until the position is filled.

Position and Version #: JOB-BPF-501 v8

Location of Position: Bozeman, Montana

Reporting Relationship: This position reports to the Senior Director of Operations

Job Classification: Salaried

Supervisory Responsibilities: Supervises the positions of Quality Assurance Manager, Analyst – Quality Control,

Analyst – Quality Control Lead, and Metrology (Calibration/Validation Technicians).

Scope of Position: This position has oversight Quality Assurance, Quality Control, Document Control, and Regulatory Affairs for Mesa Lab locations in Bozeman, MT, München, Germany – Simicon and Lyon, France). This position has the ultimate jurisdiction where quality related issues arise within the divisions of Assembly and Packaging and/or Laboratory Production.

The Director is a member of the Bozeman Management Team (BMT). The BMT has control of the manufacturing processes and procedures and is expected to successfully execute the daily operations. This position is accountable to the members of the BMT and are expected to work together to made decisions in the best interest of the organization.

Essential Duties Core duties and responsibilities include, but are not limited to, the following:

- Model personal Lean Philosophy 5S behaviors in creating a continuously improving, clean, well-organized and self-maintaining work environment. Work closely with team members and others to motivate and improve 5S knowledge and implementation.
- Follow a continuous improvement approach for team accountability for achieving high performance SQDC (Safety, Quality, Delivery, & Cost) targets through a visual work environment.
- Comply with company ethics, code of conduct, policies, and best practices, with a commitment to safety in the workplace, valuing of diversity, and promotion of a harassment-free environment.
- Responsible for oversight of the Quality System for SDC Operations as described in the Quality Manual
- Ensure compliance with federal and international regulations relating to the organization’s products and quality system.
- Ensures that procedures and work instructions are followed.
- Performs quality assessment of critical suppliers
- Oversees onsite inspections and communications with regulatory bodies.
- Completes and submits 510(k) documents to the Federal Drug Administration (FDA) for clearance on relevant products.
- Maintains compliance with ISO quality systems.
- Sets goals and expectations for direct reports.
- Responsible for signing legally binding Quality Agreements.

Essential Duties (continued)

- Ensures all QA/QC employees have the appropriate skills, knowledge, abilities, training and tools to execute their responsibilities.
- Manages/supervise employees with regards to employee relations, training, disciplinary issues, performance management, etc.
- Responsible for achieving organization and department goals.
- Controls expenses and labor costs to conform to the manufacturing budget.
- Complies with all safety and regulatory standards.
- Perform other duties as assigned by management
- Apply the Mesa Labs Quality Policy and actively monitor quality of outcomes in the performance of all assigned tasks
- Perform other duties as assigned.

Professional Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The categories listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and/or Experience:

- Bachelor's Degree in scientific or relevant field
- Five years' experience in a manufacturing environment
- Ten or more years' experience in a manufacturing environment preferred
- Experience in FDA regulated industry preferred
- Experience with ISO13485 and ISO9001 requirements
- Three or more years' supervisory or management experience preferred
- General knowledge of global Quality standards and regulatory compliance requirements
- Any equivalent combination of education and experience

Skills, Knowledge and Abilities:

- Advanced knowledge and skill with Microsoft Office programs
- Effective communication skills
- Ability to work in a team environment
- Ability to focus on continuous improvement
- Ability to take initiative and leadership on projects and tasks
- Ability to meet timelines

The Mesa Way! Expectations:

This position is a **Senior Professional** focused on individual accountability, teamwork, and cross-functional collaboration. Leadership by example at every level. Proactive daily management.

Pillar #1 – Measure What Matters

- **Customer Centric & Game Plan** - Always gathers customer insights and shares with team. Understands external and internal trends, and their impact from a customer perspective. Continually searches for ways to increase customer satisfaction. Displays strong degree of customer empathy.
- **Critical Few** – Effectively seeks the right problems to be solved, balancing immediate improvement vs. long-term breakthrough/new muscle. Proactively develops and executes improvement plans to meet annual objectives.

The Mesa Way!
Expectations (continued):

- **Clear Direction and Buy In** – Simplifies complexity to enable broader involvement, team understanding, and buy-in.
- **Stretch Goals That Drive Innovation** – Sets high expectations for team and self. Celebrates success and solves the "what" of the performance gaps vs. "who." Maintains team motivation.

Pillar #2 – Empower Teams

- **Ownership at Point of Impact** – Recruits, evaluates and hires strong people who fit, can excel, and have a passion to win. The Mesa Way! Embraces diversity, actively scouts for new Mesa talent. Create an environment of ownership by the team at the point of impact. Hiring the right candidates and develop.
- **Coach vs. Direct** – Demonstrates situational awareness and is not intimidated by conflict. Creates an entrepreneurial environment that allows for mistakes for the opportunity of learning. Directly confronts issues that derail the team advancement. Consistently treats people fairly, with respect and provides candid feedback in a timely manner. Promotes stretch/growth and understands the importance of coaching for the long-term investment. **Fact Based Decisions** – Deepen the culture of decision-making through the Mesa Way criteria. Create and foster the environment, set the example, and course correct when needed.
- **Proactive and Urgent** – Relentlessly identifies the critical few and prioritizes them. Expeditiously brings complete closure. Turns strategies/opportunities into actionable plans. Matches approach to the urgency/importance of the situation. Ensures that the holistic perspectives are leveraged.

Pillar #3 – Steadily Improve

- **Seeks a Better Way** – Models behavior of using visible metrics to measure and manage the team, outcomes, resources, and own time. Empower and coach team to solve problems. Selects the appropriate Lean tool for the problem to be solved. Drives Kaizen events as sponsor and actively contributes to cross-functional / BU initiatives. Recognizes and celebrates successes.
- **Problem Solve to Root Cause** – Effectively selects the right problems to be solved balancing immediate improvement vs. long term breakthrough / new muscle. Proactively develops and executes improvement plans to meet annual objectives. Precisely scopes and define problems. Ensures solutions balance immediate actions (go do's) and process improvements. Effectively leverage data and logic / 5 Why's to get to root cause. Does not jump to solutions. Displays rigorous A3 Thinking skills to solve most important problems. Constructs effective teams to solve problems at root cause.
- **Experiment** – Seeks and finds opportunities for improvement; generates more ideas than can be actioned. Can delineate market feedback on execution and design. Continues to learn and refine initiative throughout commercialization phase.
- **Bias for Action** – Balances fact-based decision making with learning-by-doing. Entrepreneurial. Knows when/how to cut off debate and initiate experiments to gain real world feedback. Maintains bias for action with logical framework to ensure feedback is leverageable. Not afraid to try and fail.

The Mesa Way!
Expectations (continued):

Pillar #4 – Always Learn

- **High Expectations** – Sets high expectations for team and self. Celebrates success and solves the "what" of the performance gaps vs. "who." Maintains team motivation.
- **Transparent Two-Way Communication** – Direct and honest, presents the truth transparently and with respect. Willing to admit mistakes as an opportunity for growth and improvement. Presents the unvarnished truth in a respectful and helpful manner. Promotes an environment that fosters safe and open communication without fear of retribution.
- **Passion for Teaching and Learning and Continuous Feedback** – Direct and honest, presents the truth transparently and with respect. Willing to admit mistakes as an opportunity for growth and improvement. Presents the unvarnished truth in a respectful and helpful manner. Promotes an environment that fosters safe and open communication without fear of retribution.
- **Humility and Self Awareness** – Balances their individual leadership style with Mesa norms while remaining authentic. Demonstrates humility with team. Seeks feedback from peers and team. Understands root cause of feedback. Supports others in providing honest feedback. Not afraid to stand alone and make a case, however, supports the team's decision. Mindful of impact on others. Maintains a constructive and positive atmosphere at all times.

Physical Demands:

While performing the duties of this job, the employee is regularly required to stand or sit for extended periods of time. If reasonable, requests regarding ergonomic concerns will be considered. For individuals with disabilities, accommodations may be made to perform the essential functions. Occasional lifting is required.

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.

This is a high volume, high energy manufacturing facility that works to meet manufacturing deadlines. An enthusiastic, positive attitude is highly encouraged and conducive to a productive successful atmosphere. Common sense judgments and problem solving is desirable. Must have the ability to handle repetitious and tedious job functions.

A typical office environment and biological laboratory environment comprise the bulk of the work environment for this position. The noise level in the work environment is moderately quiet.

This position requires up to 25% travel. Some of the travel is international.

Compensation:

Salary, incentive bonuses, and equity will be offered commensurate with the successful candidate's experience and qualifications. Benefits include medical, dental, vision, life, accidental death and dismemberment, short term and long-term disability, Executive Personalized Time Off, paid holidays, 401k retirement with company match.

Contact: Human Resources | twimbish@mesalabs.com | 303-987-8000 x10342

How to Apply: Submit current resume/CV to twimbish@mesalabs.com. Include the position title in the subject line.

Screening of resumes will begin **immediately**; resumes accepted until the position is filled.

*Mesa Labs is an Equal Employment Opportunity Employer.
Mesa Labor prohibits unlawful discrimination and harassment against applicants or employees based on age, race, sex, color, religion, creed, national origin or ancestry, disability, military status, sexual orientation, or any other status protected by applicable state or local law.*