Manager/Director of Quality Assurance/Quality Control

Position Overview:

Reporting to the VP of Quality, this position is responsible for implementing and managing Miach's Quality function and Quality Management Systems, ensuring that internal processes and metrics are aligned to create the highest product quality and they are in conformance with customer expectations. The Manager/Director of QA/QC is directly responsible for all work needed to maintain the quality systems that will ensure compliance within FDA QSR, ISO and other applicable regulations and standards. This role is responsible for interfacing and working with internal functions to ensure compliance to the Quality Manual, Design Control and other appropriate procedures and with external parties, including the contract manufacturer and other suppliers, on issues related to quality.

Duties/Responsibilities:

- As a member of the management team, serve as leader and champion for all aspects of the Miach Quality System, including but not limited to:
  - Product design and manufacturing processes
  - Product verification and validation
  - Design FMEA, risk analysis
  - Doc control system
  - Biocompatibility and sterilization
  - CAPA system and complaints handling
  - Continuous process improvements
- Ensure the Quality System is compliant with applicable standards and regulations for medical device products
- Support preparation of product approval PMA applications and 510(k) (if needed)
- Interface with regulatory agencies on compliance related issues
- Conduct the Quality System external audit program
  - Coordinate and manage the qualification of internal and external manufacturing operations
  - Manage quality assurance programs related to tracking, reporting and management of supplier audits
- Conduct internal audits
  - To ensure the company is trained and prepared for FDA or other notified body inspections
  - To assess organizational compliance to all relevant regulations and standards

- Conduct internal training in general quality systems, corrective actions, deviations, change management, root cause analysis, design controls and other key systems
  - Maintain and manage training records
- Responsible for the development and oversight of the Corrective Action program; recommend corrective action to the Quality System based upon internal or external quality reports
- Ensure that sterility and biological test/validation requirements utilizing appropriate industry standards are met
- Establish and conduct management reviews
- Maintain and track quality for the purposes of analysis, control and management reports; develop metrics to monitor and report on supplier quality and customer complaint trends
- Direct activities related to process and product verification/validation.
- Manage the document change control process
- Maintain awareness and communicate changing regulatory requirements that impact the quality function
- Other duties as assigned

Education/Experience:

- BS degree in engineering, a technical or scientific discipline or equivalent experience; advanced degree preferred
- Must have 5-10 years of experience in the Quality discipline and Quality Systems in an FDA regulated company
- Strong track-record in Class III medical device industry
- Successful track-record creating and installing a quality system for a new business or company
- Experience interacting with the FDA and notified bodies; experience with the FDA and ISO certification inspections
- Must be familiar with statistical principals as they relate to statistical sampling plans
- Experience in a start-up company environment strongly preferred
- Experience in orthopedics preferred
- Experience in CE mark is a plus
- Experience in compliance is a plus
- Regulatory affairs knowledge is a plus

Skills/Competencies:

- Ability to 'roll-up' sleeves and do what it takes to get job done
- High energy with a 'can-do' attitude
- Excellent verbal and technical writing skills
- Self-starter with excellent time management skills
- Must have strong attention to detail and be highly organized
- Ability to communicate at multiple levels of the organization and is effective in presenting their point of view
- Strong interpersonal skills with ability to collaborate effectively across the organization
- Strong PC skills creating spreadsheets, databases, reports