



Regulatory Affairs & Quality Assurance Manager

Description

Ensure continuous compliance and ongoing improvement to our Quality Systems. You will be collaborating across the organization as we develop and commercialise new products from concept through product development to commercialization. The role requires a strong understanding of FDA, ISO and other international quality standards and regulations.

Key Performance Indicators

1. Ensures continuous review and improvement of the quality systems to provide effective and efficient processes and assure regulatory compliance.
2. Collaborates on regulatory aspects of product development; prepares and submits new product approval applications.
3. Works collaboratively across the organization to assure compliance and implement system improvements.
4. Implements and maintains an electronic quality management and reporting system for key quality processes: customer complaints, returned goods, non-conforming materials, CAPA, internal audit, document control, training, and equipment calibration/maintenance.
5. Coordinates and oversees CAPA system.
6. Acts as Lead Internal Auditor for the Quality Management System and Supplier Audits. Coordinates audit program, conducts audits, publishes audit reports, and oversees resulting corrective actions.
7. Performs trend analysis of quality data and provides periodic quality metric performance reports to Management.
8. Participates in projects relating to product and process quality issues.
9. Supports FDA inspections.

Qualifications

- Bachelor's Degree in a technical or life sciences field
- Certified lead auditor credentials desired
- Minimum 4 years experience in quality management/compliance environment within medical device company. Minimum 2 years project management and personnel supervisory experience
- Strong understanding of FDA, ISO and other international quality regulations and standards
- Strong process mapping, development and implementation skills
- Experience implementing electronic quality management and reporting systems
- Proficiency with Microsoft Office
- Strong verbal communications, technical writing and presentation skills
- Detailed-oriented work habits. Ability to manage and prioritize multiple projects and tasks
- Collaborative and team oriented. Able to work with personnel across the organization

Location: Frisco, TX

Schedule: Full-time