Sr. Director, Product Management

POSITION SUMMARY

The Sr. Director of Product Management is a cross-functional role involving product development, commercial manufacturing, quality, regulatory, clinical support and business development activities. The Sr. Director of Product Management will serve as the quality manager for Acera, and assumes responsibility for on-going system maintenance and effectiveness of operation.

EXPERIENCE

- Bachelor degree in Science/ Engineering required
- Graduate degree in Science/ Engineering/ Ops/ Business Administration preferred
- Experience in FDA/GMP and ISO 13485 environment in medical device industry
- Demonstrated knowledge of FDA Quality System Regulations
- Demonstrated knowledge of ISO 13485 based quality management systems
- Experience with project management principles, understand critical path and budget management
- Experience with commercial manufacturing of medical devices
- Experience writing/ overseeing FDA regulatory submissions preferred

PRINCIPAL RESPONSIBLITIES (Other duties may be assigned)

- Primary liaison between contract manufacturer, sterilizer, packager and Acera Surgical
- Responsible for manufacturing, operations, production forecasting, order fulfillment, inventory management, warehousing and back-end of supply chain to fulfill customer orders
- Responsible for proactively soliciting market feedback and working with Acera team to prioritize and then manage execution of product enhancements, including claims/labeling expansion, product line extensions, updated marketing materials, etc.
- Responsible for developing and maintaining all marketing materials and collateral to support product sales and business development.
- Works closely with Regulatory and Quality consultants and other Acera team members to develop and submit applications for regulatory clearance
- Explore new vendor /supplier relationships in an effort to reduce COGS and/or improve inventory management
- Serve as the quality manager for Acera, including assuming responsibility for on-going system maintenance and effectiveness
    - Ensures that the quality system requirements are effectively established and followed/maintained
    - Reports on the performance of the quality system to the management team and on any need for improvement
    - Promotes awareness of customer and regulatory requirements via established and appropriate communication process, such as design review and management review meetings
- Support the Chief Clinical Officer on designing, implementing pre-clinical and clinical studies. Supplement reporting and publication efforts once data is obtained.
- Support Acera product management during commercial sales, clinical support or developing marketing materials.
- Manage timeline and cost for product development/enhancement activities from feasibility phase through regulatory submission and approval; responsible for collecting necessary information to assess tradeoffs, present to leadership team, and facilitate key decisions