Title: Senior Manager/Director of Quality Management Systems and Training
Department: Operations and Quality
Travel requirement: Less than 5%

Job Summary

The Sr. Manager/Director of Quality Management Systems has responsibility for managing the Quality Management System (QMS) for the company to ensure compliance with all appropriate quality standards required for the regions in which Onkos desires to conduct business including 21 CFR part 820 and ISO 13485. In addition, this role is responsible for leading Onkos' training program, ensuring that employees are adequately trained to perform their designated role(s) as well as on QMS procedures and that all training is well documented.

Responsibilities

- Adhere to Onkos' Core Beliefs and Code of Business Conduct.
- Build, develop and lead a team to execute the components of a QMS on a day-to-day basis.
- As a leader in the organization, provide sound advice and guidance regarding the impact of quality issues on overall corporate strategy and operations.
- Ensure the company remains compliant with current quality standards.
- Recommend, review and develop policies, procedures and systems to drive continuous improvement.
- Monitor changes to regulations that impact the Quality Management System.
- Lead all U.S. FDA and ISO facility inspections.
- Assist in the review and approval of promotional material to ensure compliance with the QMS.
- Identify relevant quality standards, risk management and validation requirements for product development.
- Lead efforts to ensure appropriate levels of document control are implemented.
- Provide leadership to the Quality team to ensure an effective CAPA process is maintained. Assist in root cause analysis.
- Work with managers from all departments to confirm training needs of their employees (role-based training) and implement a process to ensure training is delivered and documented.
- Promote the development of a company-wide understanding of the key elements of the QMS.
- Develop and review quality system-related metrics with senior management.
- Help drive a culture of quality and continuous improvement throughout the organization.

Requirements

- 10+ years of leadership experience in medical device Quality Assurance roles.
- Minimum of BS degree in scientific discipline, preferably life sciences, biomedical, or other engineering science. MS or PhD a plus; auditor qualifications a plus.
- Demonstrated success related to the implementation of quality systems.
- Strong experience in CAPA management
- Knowledge of current US and international medical device regulations and guidelines.
- Excellent interpersonal and leadership skills; self-motivated and flexible to changing schedules.
- Strong attention to detail, good oral and written communication skills
- Strong computer skills, including word processing, spreadsheet and data programs.