

Title: Quality Assurance Engineer
Department: Operations and Quality
Travel requirement: Less than 5%

About Onkos Surgical

At Onkos Surgical, we believe individuals with cancer requiring surgery deserve solutions designed specifically for them. These individuals, their caregivers and their support network deserve an organization passionately championing their cause. We exist to maintain a singular focus on surgical oncology by looking at everything we do through the lens of the cancer surgeon and their patients. At Onkos Surgical, we will:

- Find solutions to our patients' unmet clinical needs and advocate for their cause.
- Partner with surgical oncologists through research, education and innovation, to treat their patients more effectively and more efficiently.
- Collaborate with regulatory agencies to find pathways to provide timely solutions while upholding the highest standards of quality or compliance.
- Fulfill our employees' desire to make a difference in the lives of the patients they serve while achieving their own professional growth.
- Deliver value to our customers and shareholders.

Job Summary

The Quality Assurance (QA) Engineer will play a key role in the implementation of Onkos Surgical's Quality Management System and have the opportunity to gain experience across a broad range of quality functions related ISO 13485 and 21 CFR Part 820 compliance. Specifically, the QA Engineer will champion complaint handling, product release procedures and approval, and support to both NCR and CAPA processes. This will require developing relationships and working closely with suppliers. This position will also work with cross-functional teams to provide quality engineering support in the development of technical files to ensure regulatory compliance during product development.

Responsibilities

- Receive, document and process complaints related to product quality and patient safety.
- Conduct, coordinate and document complaint investigations.
- Review complaints for possible Adverse Events/MDRs and recommend regulatory reporting decisions. Prepare Adverse Events/MDRs to regulatory agencies in a timely manner to meet regulatory deadlines.
- Review and approve Device History Records (DHRs) and communicate closely with contract suppliers to ensure compliance with Quality Agreements and QMS procedures.
- Participate in and support NCR and CAPA investigations.
- Participate and support in the application of Statistical Methods to trend NCRs, CAPAs, Complaints, and DHR approval acceptance.
- Support in Supplier vetting process and maintaining Approved Supplier List.
- Provide support to Product Development and Operations on design transfer and process validations.
- Participate in product risk assessment efforts, including failure mode effect analysis (FMEA's).
- Monitor quality metrics and key process indicators to identify opportunities.
- Lead and/or participate in multi-departmental initiatives to implement quality improvements.
- Drive compliance of the Quality Management System and provide QMS training to necessary team members.
- Author changes to existing procedures, work instructions, and forms as necessary.
- Comply with U.S. FDA and ISO requirements, other regulatory requirements, Company policies, operating procedures and processes.

- Perform other quality assurance and quality control functions as necessary, with appropriate training.
- Assist in the review of Technical Files.

Requirements

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

- Minimum of 3-years quality assurance experience in medical device industry. Manufacturing or supplier quality engineering experiences a plus.
- Working knowledge of CFR Part 820 and 13485 for medical device products.
- Complaint investigation experience.
- BS in an engineering discipline.
- Certified Quality Engineer certification a plus.
- Experience in root cause failure analysis and change control.
- Detail oriented and experience in a manufacturing environment a plus.
- Good verbal (including presentation) and written communication skills.