



Senior Engineer I, Supplier Quality

Ashland, MA

At Terumo Cardiovascular Group, we develop, manufacture and distribute medical devices for cardiac and vascular surgery with an emphasis on cardiopulmonary bypass, intra-operative monitoring and vascular grafting. This includes a full-line of perfusion products, endoscopic vessel harvesting products and surgical stabilization products. In addition, Terumo CV Group is the exclusive distributor of Vascutek® Vascular Grafts in the U.S.

Our parent company, Terumo Corporation, is a global medical device manufacturer focused on cardiac and vascular specialties, hospital products, and home health care. Established in 1921, Terumo Corporation has more than 19,000 associates in 82 sales offices and 24 production facilities. It provides medical devices and services for the benefit of patients and medical settings in more than 160 countries.

Job Summary

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This position is responsible for serving as a resource for the Supplier Quality Engineers (SQEs) and the management of supplier corrective actions. The SQE department generates monitors and evaluates Supplier CARs, NCRs and related CAPAs. The Sr. SQE also acts as the liaison between Terumo and the supplier, providing guidance on product and component quality requirements.

Responsibilities

1. In all actions, demonstrates a primary commitment to patient safety and product quality by maintaining compliance to the Quality Policy and all other documented quality processes and procedures.
2. Manage the SCAR, NCR and CAPA elements as they apply to Supplier Quality from issuance to effectiveness checking while ensuring that acceptable parts are provided to Operations.
3. Oversee and work to continuously improve the SCAR, NCR and CAPA implementation and practices of the SQE department responsible.
4. Monitor, track, and communicate current state of supplier issue resolution to affected organizations.
5. Evaluate supplier CARs in an effort to ensure adequate root cause analysis has taken place.
6. Act as a liaison to affected areas of Terumo CVS when goods or services are rejected for supplier quality reasons.
7. Execute, jointly with supplier, continuous improvement programs as appropriate.
8. Attend meetings with Terumo management to ensure consistency of supplier status and problem resolution.
9. Represent the Supplier Quality organization on cross-functional teams. Provide project and/or program leadership as needed. Coach and guide less-experienced team members.
10. Assist in the day to-day-operations of the department (e.g., daily interaction with staff, setting goals, scheduling resources, etc.). Guide the team by example thereby ensuring consistent and timely issue identification, notification, resolution and effectiveness checking.

11. Act as a liaison between supplier and Terumo while containing, investigating, and resolving design and manufacturing issues.
12. Conduct audits at supplier sites.
13. As necessary, aid in factory transfer projects to ensure conformance to specifications, requirements, and expectations of the customer facility.
14. Write reports detailing supplier assessments, audits, first article findings, as well as recommendations so that decisions regarding product sourcing can be made.
15. Perform other duties as assigned.

Qualifications

Requires a four-year college degree in an engineering or applied science discipline and a minimum of seven years of experience in Quality, Engineering and/or Manufacturing in a high-tech industry. Previous experience with one or more of the following: Six Sigma, Failure Mode Effect Analysis (FMEA), Design of Experiment (DOE), Statistical Process Control (SPC), or LEAN Manufacturing. Intermediate computer software skills, i.e. Microsoft Office.

Competencies

The duties and responsibilities mentioned in the job description are representative of the essential functions of the position. The performance management system incorporates competencies which are identified, discussed and evaluated in order to meet operational milestones.

Four types of competencies have been identified that are tied to job families; Sales competencies are job specific skills and methods required of our sales Associates, Core Competencies for salaried and hourly Associates are the abilities and behaviors expected of all Associates in non-leadership roles, Leadership Competencies are specific abilities and behaviors required of those performing formal management roles or other leadership roles (i.e. Project Leaders).

Supervisory Responsibility

Direct: None.

Indirect: None.

Functional: This position supports various departments within the organization

Working Conditions/Physical Requirements

The position exists in office and manufacturing environments within a manufacturing facility, with minimal exposure to automated equipment. May require gowning procedures for controlled environment. May work in lab environment with chemicals, electronic equipment, and/or biohazardous materials that require the use of personal protective equipment. May require the use of eye protection, hand protection, and, depending on noise level, may require hearing protection. Requires sitting for long periods of time with occasional stooping, bending, reaching, grasping, etc. May require occasional lifting, carrying, pushing, pulling, of objects up to, but not limited to, 25 lbs. Frequent repetitive motion tasks performed.

Requires travel up to 50% depending upon site location. This may include overnight and some international travel. Non-standard hours may be required at times to support the Terumo team, product or customer requirements.

To Apply

To Apply, Please Visit the Careers Section of Our Website,

<http://www.terumo-cvs.com/>

Terumo Cardiovascular Group is an Equal Opportunity Employer