Dir. of Quality Systems Compliance

**Date:**Jan 3, 2023

**Req ID:**986

**Location:**

Phoenix, AZ, US

**Company:**Terumo Americas Holding, Inc.

**Department:**QAD-US Branch

**Job Summary**

This position is responsible for assisting the Vice President of Quality Systems Compliance in directing and conducting Quality Management System (QMS) and Product Quality / Shokiryudo assessments at Terumo facilities that manufacture products for the US market to confirm compliance with applicable US & international regulations / standards (such as 21 CFR (including Parts 7, 11, 211, 801, 803, 806, & 820); Canadian MDR; Japanese Ministerial Ordinances; ISO 13485; the Medical Device Directive; & EU-MDR).  This position is, also, responsible to assist with reporting the results of such assessments to the management staff at the local facility for purposes of determining the appropriate corrective actions that may be necessary to bring the QMS &/or production processes into substantial compliance with applicable US & international regulations / standards.  In addition, this position is responsible to facilitate communication with Terumo affiliates, as well as assist with reporting the individual & aggregate assessment results to Terumo Corporation (TC) management for awareness of the relative regulatory compliance risks, which could result in some sort of regulatory enforcement action.

This position is responsible for properly completing all assigned corporate assessment activities & assisting to assure that management is effectively informed of requirements that are necessary to establish / maintain compliance with applicable US & international regulations / standards.  Maintaining regulatory compliance is important because failure to do so can result in remedial actions ranging from internal QMS corrective actions, to product recall from the market, to litigation, &/or regulatory action by the FDA to address the situation.   This position is responsible for activities that may affect the operation of a single Terumo facility, or the entire corporation, with regards to addressing issues with a Notified Body, the FDA, or other regulatory agencies.  When appropriate, this position may assist with directing changes in company policy to ensure product safety, product effectiveness, ethical behavior &/or compliance with applicable regulations.

**Job Details/Responsibilities**

1.    Maintain training and follow applicable quality system procedures.
2.    Maintain up-to-date knowledge of applicable national / international QMS/GMP regulations, standards, guidelines and regulated industry trends.
3.    Investigate, audit, analyze, propose improvements and direct the assigned Quality Management System activities.
4.    Assist to establish, organize, monitor, & obtain agreement on the annual QAD / CQO Staff Quality Management System (QMS) & Product Quality Assessment Program in coordination with QAD / CQO Staff in Japan, as well as Quality Management staff at various Terumo facilities.
5.    Assist to direct & conduct Product Quality / Shoki-Ryudo & QMS assessments of Terumo facilities that manufacture products distributed in the US.
a.    Assessments will include supervision of global audit team resources, & collaboration with consultant support, when deemed appropriate.
6.    Provide Quality Management System (QMS) assistance for Terumo facilities including:
a.    Review of QMS improvement & corrective action plans proposed to address identified compliance risks;
b.    Advice & support for various interactions with regulatory authorities;
c.    Facilitate / optimize the growth of Terumo global human resources expertise in US Federal Regulation compliance through QMS training & development of Terumo associates on a global basis, including both US & OUS affiliates.

**Job Responsibilities (continued)**

7.    Participate in the evaluation of QMS compliance risks based on on-site observation / assessment of QMS practices, review of audit results, review of periodic Quality Reports, & preparation of periodic summary reports to Terumo senior management.
8.    Assist in the facilitation of communications with Terumo group affiliates such as:
a.    Sharing of QMS best practices & lessons learned;
b.    Immediate & Periodic Quality Reporting information;
c.    Effective QSR/FDA/cGMP training programs;
d.    Computer-based QMS compliance tools;
e.    Other communications, as deemed appropriate.
9.    Support the improvement of procedures & processes to enhance corporate integrity, encourage ethical behavior, optimize QMS practices / product quality, & minimize TerumoÃ¢ÂÂs regulatory compliance risks.
10.    Interact with industry organizations, regulators & colleagues to remain up-to-date with the ever-changing demands within the QMS regulatory compliance & enforcement environment.
11.    When requested, provide assistance with regards to compliance of other regulated processes including occupational safety, environmental protection, labor laws, transportation regulations, Sales/Marketing activities, etc.
12.    Performs other job-related duties as assigned.

Internal Contacts:  Senior management members throughout the Terumo Group, TAH, & at individual Terumo affiliates, including, but not limited to, the following: Presidents, CEOs, Vice Presidents, CFOs, CIOs, Directors, Management staff & associates in HR, Quality, Regulatory Affairs, Clinical Affairs, Facilities Engineering, Development & Technology Engineering, Materials Management, Production, Sterilization & Logistics.

External Contacts: Industry organizations, colleagues / peers, Notified Body Representatives, FDA, Health Canada and other regulatory agencies (TPA, MLHW/PMDA, MHRA, BfARM, etc.)

**Working Conditions/Physical Requirements**

**Knowledge, Skills and Abilities (KSA)**

* + Position requires a 4-year degree in a technical/science area; an advanced degree is preferred.
	+ Incumbent must possess strong verbal and written interpersonal communication skills.
	+ Incumbent must be able to address regulatory questions from regulatory agency (FDA) investigators / Notified Body auditors by successfully communicating the company's methods of compliance with the applicable regulations and standards.
	+ Incumbent must maintain up-to-date knowledge of all applicable regulations, guidelines, standards, and regulated industry trends.

Incumbent must be capable of independent decision-making for all routine business issues including interactions with the FDA, Notified Body representatives, customers, etc. and must be able to assess the level of compliance in each area

**Qualifications/ Background Experiences**

* + 10+ years in a regulated industry is required, with 5 or more years in a management position.
	+ Incumbent must have significant experience with quality systems and key regulated processes such as, design controls, process validation, injection molding, medical device manufacturing processes, sterilization, bio-safety testing of materials, controlled environments, and clinical use of medical devices is also required.

It is Terumo’s policy to provide equal employment opportunity to all its employees and applicants for employment regardless of their race, creed, color, national origin, age, ancestry, nationality, marital or domestic partnership or civil union status, sex, pregnancy, gender identity or expression, disability status, liability for military service, protected veteran status, sexual orientation, atypical cellular or blood trait, genetic information (including the refusal to submit to genetic testing), or any other category protected by law. As a Company, we value diversity of background and opinion, and prohibit discrimination or harassment on the basis of any legally protected class in the areas of hiring, recruitment, promotion, transfer, demotion, training, compensation, pay, fringe benefits, layoff, termination or any other terms and conditions of employment.