QUALITY ENGINEER I

Posting ID: EM19503017

Company Website: http://www.terumomedical.com/

Company: Terumo

Work Location: Campbell, CA

Position Type: Full-Time

Salary: DOE

College Major(s): Computer Science (CS)

College Level(s): Graduate Student, PhD.
Student, Alumni

OVERVIEW

Terumo contributes to society by providing valued products and services in the healthcare market and by responding to the needs of patients and healthcare professionals. They are one of the world’s leading manufacturers of medical devices and supplies. They perform their own research and development, manufacturing, marketing, distribution and sales of medical devices. By relentlessly pursuing excellence in everything they do, Terumo contributes to society in more than 160 countries around the world.

Quality Engineer supporting IQC, FAI, Calibration, Manufacturing, Document Control, NCMRs, Supplier Management, CAPAs, Complaints, Internal Audits, quality data analysis and works closely with Manufacturing, R&D, Supply Chain, Compliance, and Quality Engineering groups to ensure a stable manufacturing process and that the suppliers and the related purchased components or services meet specifications and other requirements.

Roles and Responsibilities
- This associate is responsible for supporting QA, manufacturing, and implementing the supplier management process.
  a. Review of all new supplier add requests for impact on quality system and required controls
  b. Facilitating and performing component/material qualifications
  c. Ongoing activities
  d. Trending of quality metrics

This associate is responsible to stay current with FDA and International requirements and industry trends in regards to regulations and expectations for industry.

Education and Qualifications
• Knowledge of national and international regulations applicable to medical devices including; 21 CFR 820 (Quality System Regulations), 21CFR 803 and 804 (MDR regulations), ISO 13485, and MDD 93/42/EE.
• Proficiency in Microsoft Office applications as well as other Document Control software applications.
• Ability to interact effectively (both verbal and written) with associates across all departments within an organization at all levels.
• Must have strong proofreading skills and organizational skills, as well as exemplary attention to detail
• Must have demonstrated initiative and ability to work independently and under supervision of senior-level employees while handling multiple tasks.

Background Experience
• A 4-year degree in engineering, scientific discipline, or similar.
• 0-2 years of experience supporting a medical device/pharmaceutical/or related environment improving quality systems for manufacturing of Class II or III medical devices.
• Must possess strong written, verbal and interpersonal communication skills
• Experience in writing SOPs and/or other documents.

Preferred Skills
• Experience in document control, equipment management, and/or supplier management

How to Apply
https://terumomedical.dejobs.org/campbell-ca/quality-engineer-i/F3DFD120EA4C42E78CC03062CAFAA26C/job/?utm_medium=XMLFeed&utm_source=Symplicity-DE&utm_campaign=Symplicity&vs=5082