COLLAGEN SOLUTIONS
MATERIALS FOR LIFE

JOB DESCRIPTION

POSITION TITLE: Sr. Quality Engineer
DEPARTMENT: Quality & Regulatory Affairs
POSITION REPORTS TO: VP of Quality & Regulatory Affairs
FLSA: Exempt

POSITION PURPOSE

The Sr. Quality Engineer is responsible for determining production standards for the company's products by helping to establish quality control systems and setting product requirement rules. You'll identify the specifications for an ideal product, determining an appropriate level of variation and monitoring quality assurance rates, while helping create solutions as part of an engineering team. Additionally, you'll work to find defects, determine the causes of those defects, and provide solutions to defected problems.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Provide direction/guidance to quality engineers.
- Provide quality insight and leadership on program teams and help establish appropriate build quality controls commensurate with use.
- Plan, develop, and execute verification testing for products under development.
- Develop and initiate methods for inspection, testing, and evaluation, utilizing knowledge in engineering fields such as electrical or mechanical.
- Develop, document, and validate inspection and test methods to support design control, in-process inspection, and final inspection activities.
- Participate in the technical review of design input specifications and design documentation for new medical devices.
- Provide subject matter expertise regarding design control, change control and risk management regulatory requirements.
- Oversee the management and maintenance of design history files, change control records, and risk management files.
- Plan and lead execution of risk management on cross functional product development teams, including risk management plans, preliminary hazard analyses, UFMEAs, DFMEAs, PFMEAs and risk management reports.
- Plan, execute or direct activities concerned with development, application and maintenance of quality standards; reports results to marketing, manufacturing, process engineering, and product design group.
- Lead, participate in, or coordinate internal corrective action initiatives.
- Participate in the development of system specifications.
- Perform or support internal quality and design control audits.
- Complete component part qualification activities, including first articles, cap studies, gage R&R, and implementation of SPC requirements.
- Support product/process transfers during pilot and manufacturing builds.
- Perform design reviews and pre-validation assessments to ensure the safe and environmentally sound start-up of new processes.
- Provide guidance and generate reports for topics involving statistical analysis, including sample size requirements, process capability analysis, regression analysis, tolerance interval analysis, and ANOVA.
- Support product/process development engineering in optimization activities by guiding design of experiments of various process parameters and analyzing data.
- Participate on cross-functional teams to develop new products and processes.

- Responsible for initiating pFMEA, process flow diagrams, process control plans, measurement system analysis (gage R&R), capability studies, etc. to ensure compliance to applicable standards (ISO 13485, ISO 17025, ISO 11737, etc.), regulations (21 CFR Part 820, EU MDR, etc.) and internal procedures.
- Work with suppliers to improve product and process quality and assist with correlations studies and inspection plans.
- Review supplier processes and process validations to assure internal and external processes are adequate to meet specification.
- Execute and support on-time completion of Design Control Deliverables.
- Support on-time execution of quality plans for internal development, OEM-based, clinical product development (CPDP), and design change projects.
- Accountable for design verification and validation planning and execution, including active cross-functional root cause analysis investigation and resolution activities.
- Lead or support risk management activities from product concept through commercialization.
- Support design test and inspection method development, and lead method validation activities.
- Ensure DHF content completion, integrity and regulatory and standards compliance; collaboratively communicate and resolve gaps.
- Support manufacturing process development and qualification for new product commercialization and product changes.
- Support internal and external audit responses.
- Support product re-certifications.
- Support the establishment of objective, measurable, discrete, and verifiable customer, and product requirements.
- Support objective component specification definitions, supplied component sampling plan development and vendor qualifications.
- Support execution of biocompatibility and sterilization qualifications.
- Contribute to implementation of new requirements and compliance with the quality management system.
- Maintain professional and technical knowledge by attending educational workshops, reviewing professional publications, establishing personal networks, and benchmarking state-of-the-art practices.

QUALIFICATIONS

- Bachelor's degree.
- 5+ years' relevant experience.
- Practical experience in manufacturing or science.

KNOWLEDGE & SKILLS

- Computer literacy and strong skills with Office 365.
- Internal Auditor ISO 13485.
- Knowledge of design of experiments and validation systems.
- Understanding of ISO 13485, GMP, HACCP and USDA and MPI, and DAWR requirements (NZ).
- Problem solving skills.
- Ability to work independently and as part of the team.
- Work in a fast-paced environment where accuracy and efficiency are key components.
- Self-motivated.
- Ability to ensure quality product.
- Ability to frequently lift and/or carry 50 lbs.

INTENT AND FUNCTION OF JOB DESCRIPTIONS

Job descriptions assist organizations in ensuring that the hiring process is fairly administered and that qualified employees are selected. They are also essential to an effective appraisal system and related promotion, transfer, layoff, and termination decisions.

All descriptions have been reviewed to ensure that only essential functions and basic duties have been included. Peripheral tasks, only incidentally related to each position, have been excluded. Requirements, skills, and abilities included have been determined to be the minimal standards required to successfully perform the positions. In no instance, however, should the duties, responsibilities, and requirements delineated be interpreted as all-inclusive. Additional functions and requirements may be assigned by supervisors as deemed appropriate.

Job descriptions are not intended as and do not create employment contracts. The organization maintains its status as an at-will employer. Employees can be terminated for any reason not prohibited by law.