APPLIED PLASTICS

JOB DESCRIPTION

Position Title: **Quality Engineer**
Reports To: **Director of Quality and Regulatory**

POSITION PURPOSE:

The Quality Engineer is responsible for supporting the implementation of a Quality Management System (QMS) and to ensure compliance of QMS activities to ISO13485:2016. Partner with management team to ensure adherence to the QMS.

ESSENTIAL FUNCTIONS - The following list of essential job functions is not exhaustive and may be supplemented as necessary based on business needs.

1. Supports the maintenance of the QMS ensuring its continuing suitability, adequacy and effectiveness
2. Corrective and Preventive Action System (CAPA) ownership
3. Customer Returned Material Authorization System (RMA) ownership
4. Manages the Equipment Qualification and Validation System (including IQ, OQ and PQ, etc)
    a. Works with Manufacturing and Engineering to draft and execute protocols
5. Nonconforming Material System (NCMR) ownership and leads the MRB process where applicable
6. Performs First Article Inspections (FAI) with QC Personnel
7. Where applicable creates and executes Measurement System Analysis (Gage R&R)
8. Interface directly with customers to support technical issues and continuous improvement
9. Support day to day operations to drive Key Process Indicator (KPI) improvements and business objectives
10. Supports the Approved Supplier List (ASL) Evaluations, Reporting and Feedback
11. Creates and edits Standard Operating Procedures, Work Instructions and Forms
12. Performs Product Quality Inspections as needed
13. Performs Measuring and Monitoring Equipment Calibration as needed
14. Performs Training as needed
15. Perform other relevant duties as assigned by supervisor

SPECIFIC JOB KNOWLEDGE, SKILL AND ABILITY

The individual must possess the following knowledge, skills and abilities and be able to explain and demonstrate that he or she can perform the essential functions of the job, with or without reasonable accommodation.

1. Full understanding of a QMS and conformance to ISO13485:2016
2. Experience in medical component or medical device manufacturing required
3. Proficient in use of metrology (hand devices, vision systems, microscopes, non-contact devices, profilometer)
4. Basic proficiency in reading drawings and blueprints

5. Ability to read, listen and communicate effectively in English, both verbally and in writing
6. Experience in customer, registrar or FDA audits/inspections a plus
7. Ability to navigate a computer ERP system, in certain modules, and perform data entry, data retrieval
8. Computer Skills – Microsoft Office Suite: Word, Excel, PowerPoint, Visio required (QMS software experience a plus)
9. Willingness to continually work beyond scope of essential duties in order to assist whenever and wherever needed to ensure company needs are met

QUALIFICATION STANDARDS

Experience:

2 to 5 years of related experience in quality engineering in medical device or medical components

Education:

Bachelor's Degree in related field

Licenses/Certifications:

Valid Class D Driver's License.

Other:

Ability to speak Portuguese preferred

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