Job Title: Quality Engineer

Job Description & Person Specification

Duties & Responsibilities include but are not limited to:

- Provide day to day quality support to the manufacturing and engineering teams.
- Manage CAPA, NC's and Customer Complaints.
- Ensure that preventive and corrective actions are taken in relation to product and Quality system deficiencies and initiate, recommend or provide solutions to product and Quality system related problems
- Participate in Root Cause Analysis.
- Provide reports/information to management on quality related issues and implement solutions to quality related issues
- Participate in internal/external audits as required
- Carry out metrology activities, relating to drawings, measurements, geometrical dimensions and tolerances
- Interface with other departments to ensure that Quality system requirements are adhered to
- Follow all environmental, health & safety rules and procedures and participate in safety and environmental activities in order to improve the workplace for all employees

Education & Experience Required:

- Degree in Quality or Degree in Science / Engineering.
- 5+yrs industry experience in a Medical Device-manufacturing or Pharmaceutical environment.
- Working knowledge of FDA/ISO Quality systems for Medical Device companies.
- New product introduction and manufacturing process transfer experience would be a distinct advantage.
- Good working knowledge of Quality System Requirements within the Medical Device Industry – ISO13485:2016 & FDA
- Quality auditor experience/certification
- Good communication skills - written and oral communication skills essential.