Medical Device Quality Engineer Resume

Job Objective

Seeking work as a Medical Device Quality Engineer in which to exercise my past experience in the field for the good of the company.

Summary of Qualifications:

- Vast experience in medical, mechanical device production, test, and inspection
- Skilled to oversee manufacturing of electrical medical devices
- Deep knowledge of FDA Medical Device Reporting and international medical device regulations
- Huge knowledge of cGMP and ISO standards of medical and pharmaceutical devices
- Immense ability to develop and document validating protocols
- Good understanding of ISO 9001: 2008, FDA 21CFR820, ISO 13485 PAP, QFD, CtQ breakdown, DfSS, SPC, AQP, FMEA and Control Plan
- Proficient with C/C++, LabView/MatLab, Failure Modes Effect Analysis (FMEA), GD&T, SPC, Root Cause Analysis, and Mistake Proofing

Work Experience:

Medical Device Quality Engineer, August 2005 – Present
Avantec Vascular, Houston, TX

- Monitored facility and implemented Quality systems for products in accordance to cGMP and ISO standards.
- Managed all engineering problems of facility.
- Determined validation program for process and product in compliance with required protocols.
- Ensured that Quality Assurance standards were maintained throughout product life cycle.
- Inspected design and manufacturing facility and performed root cause analysis.
- Trained junior staff department in implementations of various quality tools and procedures.
- Documented process and prepared reports to be presented in technical presentations.
- Provided technical support to CAPA and resolved all quality issues.

Medical Device Quality Engineer, May 2000 – July 2005
Coyote Technical & Executive Sourcing, Houston, TX

- Inspected facility and performed root cause analysis and recommended corrective actions for same.
- Analyzed process and products and implemented enhanced quality systems to processes such as six sigma and 5S.
- Coordinated with operations department and ensured that new products were produced in accordance to procedures.
- Ensured that all corrective and preventative actions were taken in required timeline.
- Prepared test methods and protocols for product development team and designed fixtures.
- Coordinate with Regulatory affairs and ensured that all documents were maintained in accordance to FDA regulation.

Education:

Bachelor’s Degree in Mechanical Engineering, Austin College, Sherman, TX