Quality Engineer

Job Overview

A mid-senior level Quality Engineering personnel who applies scientific knowledge, engineering knowledge, and ingenuity to lead quality assignments related to medical device manufacturing. The candidate ensures consistent implementation and compliance to external regulations including, but not limited to FDA Quality System Regulation (21 CFR Part 820), ISO 13485, ISO 11608 & ISO 14971.

Main Responsibilities

- Represent QA in design review meetings to review all quality aspects of new products. Work with Design & Product Development Engineers to ensure quality considerations during design and concept stage.
- Assess and approve the risk mitigation techniques implemented and whether these are consistent with the product classification, potential defect types, defect frequency, severity, patient risk, process capability, process controls – UFMEA, DFMEA, PFMEA.
- Review and coordinate with Validation for all test method and design validations.
- Provide input for product lifecycle through:

1. Data collection and analysis
2. Lead projects for continuous process improvement & review the level of control in manufacturing processes including the adequacy of current process limits.
3. Reduction of reject levels
4. Ensure there are adequate product and process controls in place for identified critical or major quality attributes/process parameters
5. Provide input on non-conformance events and Corrective Actions and Preventive Actions (CAPA).
6. Develop and maintain quality measurement and inspection systems and quality indicating measurement methods and standards.
7. Use statistical and problem-solving tools as part of delivering improvement opportunities.

- Additional Responsibilities May Include:

1. Material Review Board
2. Change Request & review board
3. Support scientific, complaint, and test failure investigations
4. Lead Quality Plan development
5. Directs the efforts of others such as engineers & technicians

Required Skills & Qualifications

- Degree in Life Science or Engineering discipline with a minimum of 5 years of experience in the medical device, pharmaceutical or biotechnology industry.
- Experience in providing quality engineering leadership to project teams in the areas of Design Controls, Process Validation, and Risk Management.
- Experienced with New Product Development.
- Demonstrate use of Quality tools/methodologies. Good knowledge of FDA, GxP, ISO 13485, and ISO 14971.

- Demonstrated and applied a broad knowledge of field of specialization through successful completion of moderately complex assignments.