

## Quality Engineer

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2009 revenue in excess of \$10 billion, Covidien has 42,000 employees worldwide in more than 60 countries, and its products are sold in over 140 countries. Please visit [www.covidien.com](http://www.covidien.com) to learn more about our business.

### Job description:

Covidien is seeking a Quality Engineer who performs functions including: design verification (Design for Six Sigma), reliability engineering, component specification / approval, process evaluation and nonconforming product analysis in a project team environment. Evaluate component and sub-assembly subcontractors to ensure device quality and conformance to standards and regulations. Ensures that components and finished devices are properly specified and inspected, and the associated manufacturing processes are properly designed, analyzed, and validated. Performs failure analysis to prevent or correct component and product failures.

**PRINCIPAL DUTIES AND RESPONSIBILITIES:** 1. Contributes as a member of product development teams representing the QA function throughout the Product Development Process. 2. Develops: • FMEA's (Design and Process). • Process Flow analysis. • Control Plans. • DOE. • Measurement Systems Analysis. • Process Capability Analysis. • Quality inspection procedures, including sampling plans, for production-level components and finished devices. 3. Performs: • Product reliability testing to facilitate continuous improvement. • Evaluation and documentation of Risk Assessments (ISO 14971). • First Article qualifications of components and subassemblies. 4. Contributes to the successful completion of Process Validation initiatives: • Write Validation Master Plans, and facilitate the qualification activities required to meet validation requirements. • Participate in the preparation of IQ, OQ, and PQ protocols, and write summary reports. • Perform statistical analysis of process data; interpret, compile and organize results. 5. Monitors supplier performance, and initiates corrective actions, as required. 6. Investigates suspected nonconforming materials and manages Material Review Board activities. 7. Ensures that all tasks are conducted in accordance with Quality System procedures.

**DEPARTMENT SPECIFIC/NON-ESSENTIAL FUNCTIONS:** 1. Attend meetings as required, such as FMEA's and Project Team meetings. 2. Assist with training Associate Quality Engineers and cross-functional team members in quality disciplines. 3. Travel to Covidien Manufacturing facilities and Suppliers.

### Requirements:

- B.S. degree in Engineering, Chemistry or associated fields, or equivalent industry experience.
- Minimum three (3) years experience in design, manufacturing, or quality engineering position (medical device experience preferred) including a minimum of 1 year process validation experience.
- ASQ Certified Quality Engineering (CQE), Certified Quality Auditor (CQA)
- Good communication skills, both written and oral, and must be computer literate.
- Knowledge of and experience in developing and manufacturing medical devices in conformance with Quality System Regulation and ISO 13485 requirements.
- Knowledge of analytical tools and methods, including statistics (Minitab preferred), DOE, and the use of computer/software packages related to design, development, and manufacturing.

To apply and to get more information, please visit [www.covidien.com](http://www.covidien.com) or mail to:

Covidien

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