

## POSITION DESCRIPTION

<b>Job Title:</b>	Quality Engineer	<b>Prepared:</b>	July 10, 2019
<b>Department:</b>	Quality	<b>Location:</b>	Gurnee
<b>Business:</b>	Ohio Medical	<b>FLSA:</b>	Exempt
<b>Reports To:</b>	Sr. Manager Quality Assurance		

## GENERAL SUMMARY

The Quality Engineer position designs, evaluates and recommends processes for efficient and quality manufacturing. Through practices of lean systems and continuous improvement the Quality Engineer focuses on long term quality solutions by leading efforts to build Quality into the manufacturing process from end to end. The Quality Engineer contributes to high-performing teams and works with various stakeholders to ensure total customer satisfaction, and on-time delivery with the overall aim of maintaining the quality of the final product while keeping the manufacturing process as cost effective as possible. They do so by following the quality management systems of the manufacturing process.

Ohio Medical is an equal opportunity employer. We evaluate qualified applicants without regard to race, color, national origin, religion, gender, age, marital status, disability, veteran status, sexual orientation, gender identity, or any other characteristic protected by law.

## KEY RESPONSIBILITIES (Include but not limited to)

- Application of Six Sigma methodologies such as process mapping, (P)FMEA, Gage R&R
- Key stakeholder in the risk management process
- Review and approve/reject investigation reports
- Work closely with production engineering, material and manufacturing to address issues
- Determines quality improvement parameters by identifying statistical methods relevant to manufacturing processes.
- Focus on eliminating process variation by creating, revising and implementing a strict set of tightly and precisely defined process/procedures/quality standards
- Establishes statistical confidence by identifying sample size and acceptable error; determining levels of confidence for equipment, processes and suppliers.
- Establishes statistical reliability by using mean time before failure, weibull 3-parameter distribution, reliability modeling, and reliability demonstration tests.
- Develops experiments by applying full and fractional factorial techniques.
- Develops sampling plans by applying attribute, variable, and sequential sampling methods.
- Maintains statistical process controls by applying demerit/unit, zone charting, x2 charts for distributions and individual-medial/range for multi-stream processes.
- Analyzes data by completing hypothesis, normal distribution, and process capability analysis tests.
- Prepares reports by collecting, analyzing, and summarizing data; making recommendations.

- Maintains professional and technical knowledge by attending educational workshops; reviewing professional publications; establishing personal networks; benchmarking state-of-the-art practices; participating in professional societies; maintaining American Society of Quality Certified Quality Engineer or equivalent qualification.
- Contributes to team effort by accomplishing related results as needed.

## REQUIREMENTS FOR THIS POSITION

### a. Professional Experience

- One (1) year experience as a Quality Engineer in pharmaceuticals or medical devices required
- Project management experience a plus
- Six Sigma certification a plus

### b. Education

- Bachelors' Degree preferred in a technical field
- High School Diploma or equivalent required

### c. Language

- English

### d. Travel (estimated % of time)

- Domestic approximately – 2%
- International approximately - 1%

## PERSONAL TRAIT PROFILE

- Excellent analytical skills and ability to continually examine things and think of ways to work better. .
- Shows meticulous attention to detail. The slightest error can cause an entire structure to fail, so every detail must be reviewed thoroughly during completion of a project.
- Excellent communication skills. Able to translate complex technical and communicate with clients and other engineers while working together on a project.
- Changes in technology happen rapidly, and the most successful engineers keep abreast of new research and ideas.
- Able to think of new and innovative ways to develop new systems and make existing things work more efficiently.
- Ability to Think Logically. Make sense of complex systems and understand how things work.
- Has excellent math skills. Engineering is an intricate science that involves complex calculations of varying difficulty.
- Has Good Problem-Solving Skills. An engineer is frequently called upon to address problems and must be able to figure out where the problem stems from and quickly develop a solution.
- Is a Team Player. Work together to make one project come together successfully.