

The QiG group is looking for **Design Assurance Engineers** who will provide Quality support for the product development process. This position will be responsible for making recommendations for system improvements in product development, process development, and the Quality department activities while serving as a project core team member.

Additional duties include but are not limited to:

- Provide regulatory compliance support for the application of the PDP system, ISO13485, and GMP principles
- Perform processes or conduct tests from detailed and non-detailed instructions to characterize, verify and validate the functionality of hardware, test procedures, or process designs
- Develop and support Device Test Solutions used in mechanical applications
- Create plans, protocols, and write related reports
- Collect and review data and compare it to expected results, product documentation, specifications, and/or past experience
- Use statistical analysis to identify failing conditions, negative trends, and root cause analysis
- Write new test plans and reports as well as create and review Change Orders
- Perform systems analysis of inspection techniques
- Create ECOs to create, correct, and align documents
- Work directly with technicians and manufacturing associates and partner with R&D and process engineers to define departmental process for data collection and documentation of results
- Communicate with all levels of management and employees as well as with external customers
- Apply knowledge of product development to ensure success from concept through human use
- Recommend improvements in products and processes and partake in design reviews
- Conduct independent Design Verification using established protocols and procedures in line with industry standard business practices for acceptance criteria and sample size justifications

**Qualifications:**

- *Education:* Bachelor's degree in Quality, Mechanical, or Computer Engineering or a related field. Master's degree preferred.
- *Experience:* 5-7 years of related experience including a minimum of 1 year experience in medical devices. Practical experience in product development and/or product manufacturing.
- *Specialized Knowledge:* Knowledge of Process Validation.
- *Special Skills:* Ability to self-direct, multi-task, and prioritize.

Please apply online to [www.greatbatch.com](http://www.greatbatch.com) job# 755 Attn: Ann M Reishus

Location: Plymouth, MN