

## Job Description



### Job Title: R&D Technician

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**Job Title:** R&D Technician

**Department:** Research & Development Engineering

☐ Exempt      ☒ Non-Exempt

#### 1. Job Description:

This position, reporting to the Director of R&D Engineering or R&D Lab Manager, under direct supervision, is responsible to perform work tasks with priority and to appropriate standards and timelines as assigned. The R&D Technician will be expected to implement and maintain high-quality standards across all Gynesonics products and services. He/She is expected to have a keen eye for detail and a willingness to acquire new skills and learn on a daily basis.

#### 2. Primary Responsibilities:

**Project Engineering Support:** As part of the project team or on an individual basis builds prototypes, clinical builds, fixtures and or equipment from detail specifications, schematics, diagrams or verbal or written descriptions. Provide status reports, testing data, etc. Prepares documentation in accordance with Quality System requirements. Collaborate with cross-functional teams to ensure timely execution of project tasks and contribute to meeting project milestones.

**Testing:** Contribute to the test design or independently design testing protocols. Perform testing, trouble shoot product prototypes and complaint returns, equipment and or fixtures in accordance with Engineering and Quality system requirements. Conduct hands-on experiments and execute test plans to assess the performance, functionality, and safety of medical devices.

**Research:** Collect and analyze test data using appropriate software tools and document the results accurately and comprehensively. Research vendors and materials, as part of the development process for new and enhanced products. Maintain detailed records of laboratory activities, experimental procedures, and test data in compliance with regulatory requirements and internal documentation standards.

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**Manufacturability:** Participate in design requirements for new products and product enhancements to facilitate transfer of products to manufacturing in a timely and reasonable fashion. Work with manufacturing team to transfer product.

**Production:** In accordance with Process Instructions build product for clinical use and/or coordinate building activities at outside manufacturing company. Assist in the assembly and disassembly of prototype devices and contribute to the improvement of device manufacturing processes.

#### Other Duties as assigned

### 3. Knowledge, Skills, and Experience Requirements (check all that apply):

- 5 years minimum experience as R&D technician in medical device design or similar products.
- Ability to design and implement product testing and data collection.
- Experienced working under regulated quality systems such as GMP's, ISO, and the MDD.
- Ability to draft and execute test protocols.
- Working knowledge of GLP.
- Familiar with Design Control procedures and requirements.
- Excellent communications skills (both written and verbal) required.
- Ability to work independently or in team setting required.
  
- Required Medical Device Experience:
  - ☒ General Medical Devices
  - ☐ Specific or Similar Medical Devices
  - ☐ None Required
- Regulatory Experience:
  - ☒ QSR
  - ☐ ISO 13485
  - ☐ None Required
  
- Required Risk Management Experience:
  - ☐ ISO 14971
  - ☐ Risk Management Techniques
  - ☒ General Knowledge
  - ☐ None Required
- Required Design Control Experience:
  - ☒ Working with Medical Device Design Control Processes
  - ☐ General Knowledge
  - ☐ None Required

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- Required ESD Experience:

- ☐ Working within ESD Environments
- ☒ General Knowledge
- ☐ None Required

- Required Certifications:

- ☐ Lead Auditor Certification
- ☐ ASQ Certification
- ☐ Certified Engineer
- ☐ Other Certifications: \_\_\_\_\_
- ☒ None Required