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| **Date Prepared:** |  |
| **Employee Name:** |  |
| **Job Title:** | **Pre-production Quality Assurance Manager** |

**Position Summary:**

Responsible for overseeing all aspects of the design control process, including project management, design control documentation, and regulatory applications.

**Reporting Structure:**

Reports to Associate QA Director

**Direct Reports:**

N/A

**Major Responsibilities:**

* Responsible for identifying and completing the appropriate documentation required for new design and design modifications including but not limited to design change form, product initiation requests, design input and verification documentation, design transfer documents, design validation documentation modifications, technical file updates, etc.
* Responsible for accuracy of design transfer activities including but not limited to product and process procedures and documentation, quality system procedure, device master records, product labeling specifications, etc.
* Acts as the project leader for new product development and design changes.
* Quality approval for DCNs
* Prepare Regulatory Applications
* Initiation of supplier approval requests and risk assessment documentation

**Secondary Responsibilities:**

* Perform special tasks per request by the Associate QA Director

**Education:**

* College degree preferred

**Experience:**

* A minimum of 5 years experience in the medical device industry.

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| Employee Approval |  | Date |  |
| Supervisor Approval |  | Date |  |