Quality Systems Records Associate (Temporary Position 3-6 Months)

POSITION SUMMARY: Reviews and maintains DHR Traveler/ Traveler files of all the Quality System Records that make up the Device History Records of medical devices manufactured by SSMP. Works autonomously to collect, review, oversee correction of, and file these records. Maintain the Records room by scanning and filing documents/records, boxing up old records for offsite management. Help with other quality systems in record management.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Clean the records room, send old documents to offsite storage
- Scan records and file records away
- Reorganize the equipment files (re-create files)
- Create training files for all SSMP employees
- Updates and reorganization to records currently released in EtQ to prepare for Reliance.
- Maintain secure storage of these records and provide controlled access to other SSMP personnel
- Perform similar function on other records used to demonstrate compliance to other company procedures such as Preventative Maintenance, Calibration, and control of the Controlled Environment Rooms.
- Perform Product Release on external products.
- Perform other QA duties to support department

EDUCATION/CERTIFICATION: High school diploma or equivalent is required. An AA degree is preferred

EXPERIENCE REQUIRED:

- At least 2 years experience in the production or quality department, record keeping requirements of a medical device manufacturer or FDA regulated environment
- Experience at a small or startup medical device manufacturer a plus

REQUIRED KNOWLEDGE:

- Knowledge of industry regulations and standards such as FDA QSR, ISO 13485 and AIMD
- Knowledge of good record keeping practices

SKILLS/ABILITIES:

- Excellent attention to detail; thorough and patient
- Ability to work in a collaborative, team environment
- Proficiency with Microsoft Word and Excel a plus