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JOB DESCRIPTION

Position Title:	Quality Manager
Reports to:	Director of Quality
Department:	Quality
FLSA Status:	Exempt

PURPOSE OF JOB: Responsible for management of the quality assurance department and quality systems to support R&D, clinical and commercial manufacturing of implantable combination products (drug/device).

MAJOR DUTIES AND RESPONSIBILITIES:

- Hire, train, and manage Quality Assurance staff
- Manage the Quality Inspection functions (IQA, In-Process, Lot Release, RGA)
- Manage Lot History Record review and product release processes
- Manage Material Review Board and Non-Conforming Material Report system
- Manage the Document Control and Training functions
- Mange Supplier Selection and Approval process, including conducting supplier audits
- Administer Quality System related databases and logs (e.g. QCBD, NCMRs, IQA, Retains)
- Maintain current knowledge of federal and state and international regulations and guidances regarding combination products (drug/device) including but not limited to; QSR, cGMP, ISO, ICH, etc.
- Responsible for developing, trending and reporting quality metrics to Senior Staff
- Proactively champion quality assurance issues where applicable in company-wide activities
- Conduct regular employee training in QSR, cGMP and ISO regulations
- Develop, review and approve Quality System procedures and documents including SOPs, WI, Test Methods, Specifications, various Protocols and Reports, etc…
- Periodically inspect production areas and facility to ensure QSR/cGMP compliance
- Participate in inspections for FDA, FDB, Notified Body and other regulatory agencies
- Thoroughly document all issues related to quality assurance, QSR, GMP and ISO compliance
- Support R&D projects as assigned
- Support company goals and objectives, policies and procedures, QSR, and FDA regulations

EDUCATION /EXPERIENCE REQUIREMENTS:
BS in life sciences, chemistry, engineering, or equivalent preferred. Minimum ten years related experience in the medical device or pharmaceutical industry, in addition to a minimum five years of supervisory experience. Preferred experience with combo drug/device products.

OTHER QUALIFICATIONS: Excellent communications and time management skills required. Must work independently and be able to manage tight timelines and changing priorities.

This job description is not all inclusive. Incumbents may be required to complete other miscellaneous responsibilities as required.