

JOB DESCRIPTION

DEPARTMENT:	Clinical Affairs
POSITION:	Manager, Clinical Affairs & Reimbursement
POSITION REPORTS TO:	SVP Science & Technology
HR JOB CODE:	MGRCAR
FLSA STATUS:	Exempt

SUMMARY:

This position will be responsible for Ventus' research regarding how our devices interface with the human body. The job will include such tasks as developing clinical protocols and tests, execution of the device logistics of these clinical studies, and analysis/communication of results. The job also includes tasks to support obtaining initial reimbursement coverage and responding to customer reimbursement questions. This key position works with all departments of the company to integrate design, marketing, reimbursement, medical, quality, and regulatory aspects of our products.

This position requires strong leadership skills and the ability to manage people, deliver on multiple clinical projects. This person will manage project plans and develop clinical evaluation projects; this includes oversight on clinical strategy, investigation clinical plan, and conducting clinical studies that have been determined to meet a medical/regulatory (safety and efficacy), reimbursement and/or commercial need. This person may serve as medical/scientific consultant to marketing or research project teams and government regulatory agencies.

ESSENTIAL JOB DUTIES AND RESPONSIBILITIES:

- Aids in the development of overall company objectives and long-range goals and provides leadership in the determination of study objectives, strategy, scope and schedule in order to meet business needs.
- Works with independent clinical research groups who are proposing/conducting investigator initiated research studies to define/refine study protocols, track progress of clinical trials and support publication of results.
- Develop small scale company initiated clinical protocols through interactions with internal and external experts (e.g. product verification and validation testing, registry studies, usability testing).
- Manage clinical research organizations (CRO) through the completion of larger scale company initiated clinical protocols.
- Create budgets and schedules for clinical studies.
- Manage/perform the logistics of clinical trial execution including IRB submissions, development of clinical forms, and data collection.

Form, Job Description

- Write clinical study reports and aid in article preparation for publication.
- Communicate results of clinical trials to all aspects of Ventus personnel.
- Monitor and/or interpret results of clinical investigations in preparation of a device application.
- Successful interactions with key functional groups which may include quality control, investigators, biostatistics, data management, product development, manufacturing, marketing, reimbursement, finance, legal and regulatory affairs.
- Establish operating policies and procedures that affect subordinate organizational units. Interprets, executes, and recommends modifications to organizational policies.
- Translate clinical research into strong value propositions for government and commercial payers
- Monitor payer policies and communicate their impact to Ventus personnel
- Support the sales team in managing clinical- and reimbursement-related inquiries from customers

QUALIFICATIONS, ESSENTIAL SKILLS AND ABILITIES:

- Seven years of progressive experience in clinical operations
- B.S., M.S in a science related discipline and/or equivalent in education and experience
- Certification desirable
- Experienced in short-term and long-term business planning
- Proficient in protocol review
- Knowledgeable in FDA approval processes
- Track record of success with investigators and sponsors
- Strong organizational, project management, and interpersonal skills.
- Strong presentation, communication (oral and written) and leadership skills.
- Experience managing and providing leadership for clinical study personnel desirable.
- Occasional travel required.

Employee Signature: _____ Date: _____

Signature of the Hiring Mgr: _____ Date: _____