Job Description

Position Title: **VP of Clinical Affairs**

Report To: **CMO (Chief Medical Officer)**

Department: **Clinical**

PURPOSE OF JOB: The primary responsibility of the VP, Clinical Affairs is oversight and management of the conduct of global pre- and post-market clinical studies sponsored by Aerin. Paramount in this responsibility is the strategic planning and efficient utilization of internal and external resources necessary to support clinical studies following all required national, regional, and local regulatory governance and Good Clinical Practice (GCP).

Primary tasks would involve, but not be limited to: Development and management of highly-motivated personnel creating a cohesive Clinical Affairs department, assist with the strategic clinical investigational planning supportive of corporate objectives, clinical study internal and external resource allocation, oversight on all data management activities pertaining to clinical studies, maintenance of departmental budgets, and, as requested, representation of the Clinical Affairs department at all regional and national regulatory body and society meetings with CMO.

The position requires a high level of innovative thought, time and people management, and problem-solving skills. Tasks will need to be prioritized and responsibilities delegated to ensure department and company success. In addition to the above responsibilities, the VP, Clinical Affairs is required to interact with multiple departments within the organization as well as investigators, site coordinators, IRB chairpersons, hospital or office staff and regulatory bodies.

MAJOR DUTIES AND RESPONSIBILITIES:

- Oversee the Clinical Affairs departmental activities in support of global clinical studies following the Quality Management System
- Direct all local, regional, and national activities in support of clinical studies
- Provide direction for Clinical Affairs department members including setting goals that are aligned with corporate objectives, clinical project management and building high performance teams
- Assume the Clinical Affairs department supervisory management role of, but not limited to, personnel hiring, periodic reviews, and expense control.
- Perform, oversee, and work closely with internal and external resources to comply with GCP guidelines completely and accurately in the conduct of clinical studies.
- Support the training of internal staff, study investigators and other site personnel on the proper conduct of the trial and the review of specific product performance specifications
- Ensure the procedures and techniques are being properly performed by investigators, site personnel, and the clinical field team members to mitigate risks associated with study devices and patient management.
- Problem solve and define a solution matrix for all clinical study issues as they arise.
- Develop and maintain cost controls within the Clinical Affairs Budget
- Communicate regularly with CEO and CMO on the status of all ongoing clinical studies
- Provide strategic feedback to CEO and CMO on planned clinical activities in support of clinical objectives
- Maintain a high level of product knowledge and scientific changes impacting the ENT market.
- Develop, periodically review, and implement necessary operating procedures for department success
- Assist with all Regulatory submissions, as requested

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EDUCATION REQUIREMENTS:

- BS/BA in relevant field (advanced degree preferred).

EXPERIENCE REQUIREMENTS:

- 5 to 10 years industry experience in a medical device company.
- 5 years' experience directing a Clinical Affairs department with multiple study completions and peer-reviewed publications.
- Demonstration of team hiring and development skills through previous work experience
- Demonstration of excellent communication, presentation, analytical, interpersonal, and problem-solving skills through previous work experience.
- Ability to present/teach detailed technical and clinical information, to all levels of company personnel and customers.
- Familiarity with regulations pertaining to clinical research
- Experience in 510k clinical studies for regulatory submission, health economic studies, etc. Working with a high growth startup company a plus.

TRAVEL REQUIRED: 40%

Domestic travel is a requirement and may be heavy in periods tied to clinical activity and specialty meetings. Overall, it should be limited to less than forty percent of the time.