VP Clinical Affairs

A medical device company which is developing a revolutionary implant for the treatment of heart failure, is looking for a VP Clinical Affairs that will design and execute clinical studies from FIH to pivotal.
Responsibilities include:
1) Oversee the Clinical Affairs activities in support of global clinical studies
2) Oversee site management
3) Perform, oversee and work closely with internal and external resources in the conduct of clinical studies
4) Support the training of internal staff, study investigators and other site personnel on the proper conduct of the trial
5) Ensure the procedures and techniques are being properly performed by investigators and site personnel
6) Oversee preclinical studies to support regulatory submissions
7) Problem solve and define a solution matrix for clinical study issues as they arise
8) Develop and maintain cost controls within the clinical affairs budget
9) Responsible for Collecting quality data and analyzing this data from Company's researches and external sources.
10) Assist with all company's activities and regulatory submissions, as requested
11) Provide clinical inputs to Management and R&D.

Requirements:
• B.A / BS is required, MS or PhD in life science field is preferred
• Direct experience in Clinical Affairs Program Planning and execution of pre- market trials across multiple geographic regions, including understanding of clinical strategy, clinical operations and the scientific, statistical, regulatory and compliance requirements of clinical research
• Recent experience in the medical device industry
• 10+ years within Clinical Research and/or new medical product development
• 5+ years proven track record with medical device class III clinical affairs
• Able to travel international up as business and clinical needs are identified
• Excellent oral and written English

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