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Senior Clinical Research Associate

The Senior Clinical Research Associate is responsible for assisting the Clinical Research Team in the management and coordination of assigned clinical research studies, in compliance with FDA regulations, GCP guidelines and SOPs. May serve as a liaison with CROs to ensure quality service and clinical study conduct. Ensures that the clinical study sites, CROs and other vendors are in compliance with GCPs and relevant SOPs. Tracks activities associated with clinical trials. Under direction of a Clinical Research Management prepares necessary clinical documents and study-related documents, such as assigned portions of a protocol, protocol amendments and study operations manuals. Provides direction to CRO Clinical Research Associates. Has primary responsibility for collection of essential regulatory and other study-specific documentation related to assigned projects. Responsible for updating assigned SOPs pertaining to management of clinical studies and Clinical Research Department activities according to GCP. Assists with the processing and tracking of MRI scans and payments. Works with internal staff and consultants. Other duties may be assigned.

Requirements

- Minimum BS in biology or healthcare required (MS preferred)
- Clinical Research 5+ years, in device, biotech, pharma or CRO setting
- Experience working with international and U.S. regulatory bodies, such as Notified Bodies, Competent Authorities, FDA or EMEA
- Preferred understanding of plastic and reconstructive surgery, implants and related products
- Knowledge of principles of clinical research study design and approaches to statistical analysis
- Strong knowledge of Good Clinical Practice (GCP) and U.S. and international regulations for clinical trials
- Clinical research professional certification preferred
- Able to travel up to 30% of time