Position: Clinical Documentation Specialist (temp)
Reports to: Associate Director, Clinical Operations
Location: Waltham, MA

Description: Responsible for assisting and providing support to the entire Inspection Readiness Project Team Members e.g., NDA and Inspection Readiness Lead, GCP documentation specialist, Clinical Project/Trial Managers, Regulatory, etc.) in the management of all TMF related activities including the planning and execution of in-house or outsourced TMF activities. The CDS and will be responsible for continuous review of the TMF to ensure that the TMFs are inspection ready. The CDS performs work within established study protocols under supervision from the Inspection readiness lead or designees.

Job Responsibilities:

- Manages the Trial Master Files (all of the documents that support the clinical trials- everything that the FDA and regulatory agencies review)
- Support for clinical, data management, medical writing, safety, clinical supplies (Global Clinical Development Operations)

Job Requirements:

- Processing, filing and tracking of Trial Master File (TMF) documents (paper and/or electronic) in accordance with study-specific TMF Roadmaps
- Performing quality checks of TMF documents as needed
- Providing oversight of TMF quality checks performed by functional areas and/or CRO's
- Assisting with audit and inspection preparation as applicable

Must Have:

- 2 years minimum experience doing anything associated with TMF (Trial Master Files) or Clinical Documentation
- GCP Experience preferred
- Clinical experience
- CTA/CRA experience preferred
- Experience with using an electronic document management system and proficient in excel necessary
- Must be pro-active team player, flexible, and open to change

Apellis is…

A clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

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