



JOB TITLE: Document Specialist
DEPARTMENT: 200 – Clinical/Regulatory

ABOUT BRAINCELLS:

BrainCells Inc. (BCI) is a biopharmaceutical company focused on the development of breakthrough small molecule therapeutics for diseases of the central nervous system (CNS). The Company's technology platform is based on pioneering research in the field of neurogenesis and recent discoveries linking neurogenesis to CNS disease states (for details of the scientists and clinicians involved in the company see <http://www.braincellsinc.com/company/people/scientific-advisory-board>).

BCI is using its neurogenesis technology platform to identify clinical-stage compounds, novel targets and compounds optimal for CNS indications. BCI is building a pipeline of clinical-stage programs to address unmet medical needs in the treatment of mood disorders, psychoses, cognition, brain repair syndromes and other CNS disorders.

SUMMARY:

Seeking a candidate with a minimum of 3 years of experience of relevant records management work in Quality Assurance, Regulatory Affairs or Clinical Trials Management in an FDA regulated industry or equivalent. Directed training related to any of the following disciplines: Regulatory submissions, Clinical Trials data or records management, GMP, GLP, GCP Document Control, or Library Science would be an advantage. In-depth understanding of the various TMF document types, including but not limited to, recognition and understanding of document type purpose as well as the key data on each document type preferred. Knowledge of FDA, EMEA, ISO, ICH and GCP concepts, regulations and guidelines is necessary. The successful candidate would be expected to contribute to and integrate significantly into a team environment.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Filing and maintenance of all BCI documents intended for submission to FDA, other regulatory agencies and/or for publication. Includes all non-clinical and clinical draft and final reports, as well as CMC data reports.
- Managing operational aspects of Corporate Records including Intellectual Property documentation, Contracts, and Agreements.
- Managing the Regulatory Record Center and associated areas of controlled documentation including GMP, GLP, and CMC records, Clinical Trial Master file records, Regulatory Submissions, Quality Assurance audits, and other associated files.
- Receiving, processing, and archiving of documents including the management of off-site vendors, including storage, scanning, and OCR.
- Maintaining the security and integrity of corporate, regulatory, clinical and CMC records.
- Maintaining timely throughput of records processing, both Corporate and Regulatory.
- Servicing internal customers with timely document processing and retrieval from electronic document management systems.
- Maintaining the Records Management and Archive database system.
- Ability to smoothly handle surges of work.
- Expand and maintain a proper filing system for all regulatory documents.
- May supervise temporary staff.
- Performs other duties as assigned.



KNOWLEDGE/SKILLS/ABILITIES REQUIRED:

- Minimum 3 years of relevant records management experience in Quality Assurance, Regulatory Affairs or Clinical Trials Management in an FDA regulated industry or equivalent.
- Bachelors Degree in a related field (information science, library science, biological sciences) preferred
- Directed training related to any of the following disciplines: Regulatory submissions, Clinical Trials data or records management, GMP, GLP, GCP Document Control, or Library Science.
- In-depth understanding of the various TMF document types, including but not limited to, recognition and understanding of document type purpose as well as the key data on each document type.
- Knowledge of FDA, EMEA, ISO, ICH and GCP concepts, regulations and guidelines
- Detail-oriented with a strong organizational, documentation and proofreading skills.
- Ability to multi-task and meet deadlines
- Self-motivated, team player with the ability to work independently, when necessary, in a fast paced, dynamic work environment
- Electronic document management and/or scanning/imaging experience a plus
- Proficient in Microsoft Office software and familiarity with general office equipment (copiers, scanners, etc.)
- Ability to change tasks quickly and still maintain attention.
- Ability to regularly lift, push or pull up to 50 pounds.

PHYSICAL DEMANDS:

- While performing the duties the employee is:
 - constantly required to reach computers and other office equipment
 - constantly required to view objects at close and distant ranges
 - frequently required to communicate with others
 - frequently required to sit
 - frequently required to stand
 - frequently required to use fine manipulation and simple grasping and to utilize the computer and other standard office equipment such as telephone, fax machines, copiers, etc.
 - frequently required to lift and transport items weighing up to 50 lbs.
- Equipment typically used: Computers and other general office equipment.

Note: For the purpose of this summary, occasionally is used to represent up to 1/3 of the time given to the work day, frequently represents 1/3 to 2/3 of the time and constantly represents 2/3 or more of the time.

To apply, send cover letter and resume to hrdirector@braincellsinc.com.

WORK ENVIRONMENT:

Employee frequently works in an office environment with a moderate amount of noise and activity. The work environment is fast-paced and demanding. Overtime duties may be required as assigned by manager.

Employee's acknowledgement: I acknowledge by my signature below, that the duties listed on this job description represent those tasks falling within my immediate responsibility. I must inform my immediate supervisor and the Human Resources Department should I have a significant change in duties and responsibilities after signing this job description.

Signature of Employee

Date

Print name of employee

Document Specialist