RA Associate

Jerusalem, Israel

Gamida Cell is a clinical-stage biopharmaceutical company committed to developing novel cell therapies with the potential to cure difficult-to-treat cancers and rare, serious hematologic diseases. We are leveraging our proprietary nicotinamide-based cell expansion technology, or NAM technology, to develop product candidates designed to address the limitations of current therapies. Gamida Cell is a publicly traded company (NASDAQ: GMDA).

Omidubicel, Gamida Cell's lead investigational product candidate, is an advanced cell therapy in development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution. Omidubicel is currently being evaluated in an international, multi-center, randomized Phase 3 study in patients with high-risk blood cancers. Additionally, the company is developing GDA-201, an investigational, natural killer (NK) cell-based cancer immunotherapy in Phase 1 development in patients with non-Hodgkin lymphoma and multiple myeloma.

KEY RESPONSIBILITIES

1. Critical review of development reports, review of validation reports, stability reports, pre-clinical and clinical protocols and reports which are part of regulatory submissions
2. Summarize, compile and review of documents to prepare regulatory submissions and dossiers
3. Manage preparation of submission files, including coordination of input and review by different functional teams and consolidation of their feedback, maintaining high quality and adherence to timelines
4. Review and write controlled documents and SOPs related to regulatory activities

QUALIFICATIONS

- At least two years of global RA experience in pharmaceutical/biopharmaceutical industry, including quality and clinical aspects
- Experience with managing of global registration of new investigational products
- Experience with various submissions to FDA, EMA and local EU authorities
- Understanding and knowledge of FDA and EMA regulatory guidelines for human drugs
- Good scientific understanding and deduction capabilities
- Basic knowledge of GMP and GCP principles
- Technical and regulatory writing skills
- Excellent verbal and written communication skills in English
- Meticulous and paying attention to details
- Good knowledge in Microsoft Office
- Team player, strong analytical skills and ability to work with a minimal supervision, under pressure and meet deadlines
- Good personal communication and interaction capabilities
- Advantage: MSc degree in biology/biotechnology, experience and knowledge in cell therapy

EDUCATION

- Bachelor's degree in a Life Sciences related field (Biology/Biotechnology/Medical Sciences) or B.Pharm

Reports to RA Director