Mighty Therapeutics, Inc. is an innovated biopharmaceutical company pioneering a new class of medicines that directly target mitochondrial dysfunction, improving quality of life for individuals who have long faced limited options. Driven by a desire to help patients with unmet medical needs, our team collaborates with well-recognized institutions, physicians, and scientists to develop the next generation of therapies focusing on mitochondria dysfunction in many diseases.

Position Title: Director, Pharmacovigilance (PV) Operations

Position Summary:
The Director, Pharmacovigilance (PV) Operations is responsible for the strategic leadership, oversight, and execution of global pharmacovigilance operational activities supporting clinical development, expanded access, and commercial products. This role serves as the operational leader of the PV function, ensuring a scalable, inspection-ready pharmacovigilance infrastructure that meets global regulatory requirements and supports the company's transition from development-stage to commercial-stage operations.

The incumbent will oversee PV vendors, safety systems, compliance activities, aggregate reporting operations, quality management, and process optimization. Working closely with Safety Physicians, Clinical Development, Regulatory Affairs, Quality, Medical Affairs, and external partners, this individual will ensure efficient and compliant execution of global safety activities while driving operational excellence and continuous improvement.

Responsibilities:
- Develop and execute the pharmacovigilance operational strategy to support ongoing clinical development programs, expanded access and commercial products
- Establish scalable processes, governance structures, and operating models that support organizational growth
- Establish and monitor key performance indicators (KPIs), escalate issues and drive Corrective and Preventive Actions (CAPAs) as warranted
- Provide end-to-end oversight of pharmacovigilance vendors, including case processing, aggregate reporting, literature surveillance, safety systems, and call center providers, as applicable
- Maintain a state of continuous inspection readiness across all pharmacovigilance activities
- Serve as PV lead in preparation for regulatory inspections, partner audits, and due diligence assessments
- Ensure effective oversight and inspection readiness of outsourced PV activities
- Support vendor selection, qualification, contracting, and implementation activities
- Partner with Quality Assurance to establish and maintain compliant pharmacovigilance processes, Standard Operating Procedures (SOPs), work instructions, and training programs
- Provide operational oversight for the preparation and submission of aggregate safety reports and for safety updates supporting regulatory submissions and health authority interactions
- Monitor incoming safety information from all sources and ensure operational support for signal detection, safety surveillance, and risk management activities
- Participate in safety governance meetings

- Partner closely with Clinical Development, Regulatory Affairs, Medical Affairs, Biostatistics, Clinical Operations, Quality, and Medical Writing to ensure alignment of safety activities
- Provide internal and external operational support for pharmacovigilance activities (e.g., investigator training and adverse event reporting training)
- Review safety-related sections of clinical development documents (e.g., protocol safety reporting language, alignment of patient Informed Consent with Investigator Brochure)
- Support regulatory submissions, product launches, business development activities, and partnership due diligence efforts
- Support the development and compliant execution of Safety Data Exchange Agreements (SDEAs) with partners
- Serve as business owner for pharmacovigilance systems and technologies
- Oversee implementation, maintenance, enhancement, validation support, and governance of safety databases and related platforms
- Drive operational excellence through process standardization, automation, and continuous improvement initiatives
- Monitor evolving global PV regulations and ensure operational processes remain compliant

Competencies:

- Strong working knowledge of global pharmacovigilance regulations, including FDA, EMA, ICH, and GVP requirements
- Experience overseeing outsourced pharmacovigilance models and vendor governance
- Experience supporting regulatory inspections, audits, and quality management activities
- Experience implementing or managing Argus, ARISg, Veeva Safety, or comparable safety systems
- Experience supporting commercial launch readiness activities
- Excellent oral and written communication skills
- Outstanding interpersonal skills and ability to develop a rapport with cross-functional partners that enable highly effective collaboration
- Flexibility in a changing environment (e.g., balancing individual priorities vs. evolving organizational needs)
- Ability to act expeditiously with deliberateness and intention
- Continuous strong focus on meeting or exceeding expectations in executing deliverables, performance and results
- Ability to track and measure performance against defined metrics
- Self-starter with high degree of energy, independence, initiative, and self-motivation, as illustrated by the ability to instill a sense of pace and urgency into the team
- Someone who moves fast and decisively in a balanced manner, with a passion for the growing company
- Passionate, collaborative, creative, willing to take prudent risks, and motivated by the creation of a company focused on transformative treatments for patients and their families

Requirements:

- Bachelor's degree in nursing, pharmacy, or other healthcare-related discipline; advanced degree preferred

- 10+ years of pharmacovigilance experience within biotechnology, pharmaceutical, or CRO environments
- 5+ years of leadership experience in pharmacovigilance operations, vendor management, or safety systems
- US licensure preferred (if applicable)