Assc Director/ Director; Pharmacovigilance Operations (level based on experience)

Checkmate Pharmaceuticals is a clinical stage company that is leveraging its expertise in the field of CpG oligonucleotides to discover and develop immunotherapies designed to increase the efficacy of existing immunotherapies and to provide new treatment options for patients and their healthcare providers. Checkmate’s lead product candidate, CMP-001, is an investigational cancer immunotherapeutic that has been shown to reverse resistance to PD-1 therapy in some patients. Checkmate is a privately held company headquartered in Cambridge, MA.

Checkmate Pharma is recruiting for a Director; Safety/Pharmacovigilance Operations. This DSPV leader will be responsible for refining and overseeing the Checkmate Pharma drug safety and pharmacovigilance operations in compliance with regulatory standards, and to evaluate adverse event and other safety data generated to support clinical and preclinical programs.

Responsibilities:

- Work with cross-functional team members to ensure accurate and efficient safety data collection from clinical trials
- Develop and oversee global SOPs and policies to ensure compliance with DSPV regulatory requirements (e.g., CIOMS, EMA, FDA, ICH, etc.)
- Ensure compliance with global regulatory drug safety and pharmacovigilance reporting requirements
- Provide oversight to third party vendors who have day-to-day operational activities related to safety and pharmacovigilance for investigational products
- Assist in production and revision of clinical trial documents and report forms
- Create and maintain an effective signal tracking process that fully documents signaling activities and can be used for regulatory inspection
- Search and retrieve safety data from safety and clinical trial databases for inclusion in external and internal reports
- Draft aggregate data summaries for medical review (e.g. DSURs, PSURs),
- Contribute to periodic safety and clinical study reports
- Provide PV input as a member of the study safety team
- Maintain company Reference Safety Information in line with company medical opinion
- Work with quality assurance colleagues to address safety related GCP compliance issues and implement corrective action
- Identify opportunities for process efficiencies and participate in process improvement initiatives.
- Other duties as assigned

Qualifications:

- Bachelor’s degree in a health-related field. Advanced degree in life sciences, nursing, pharmacy or medicine, (eg. PhD, PharmD, RN, MPH) is preferred
- At least 5-8 years of experience in PV Operations for a biotechnology or pharmaceutical company in the clinical trial and post marketing environments (including managing PV vendor relationships)
• Thorough knowledge of FDA and EMA safety regulations, ICH Guidelines, Good Pharmacovigilance Practice (GPvP) and other applicable regulatory guidance documents.
• Thorough knowledge of aggregate safety reporting requirements and process (e.g. DSURs, PSURs),
• Thorough understanding of the drug development process and context applicable to safety surveillance activities
• Knowledge of MedDRA terminology and its application
• Excellent written and oral communication skills, strong attention to detail, and high-performance standards for quality

Candidates must be authorized to work in the U.S.
This is a full-time position and is eligible for company benefits.
Some travel may be required

Checkmate is an EEO employer

Send resumes to: careers@checkmatepharma.com