Position Overview
The GVP/GCP Auditor will manage and/or assist in all Quality Systems aspects of Clinical Operations, Global Drug Safety and Pharmacovigilance, Regulatory Affairs, Medical Information and Medical Affairs compliance and other activities, including documentation review, internal process audits, investigational site, external vendor and commercial partner audits and follow-up. This individual will provide guidance to Clinical Operations, Global Drug Safety, Medical Information/Medical Affairs and Regulatory Affairs ensuring appropriate systems and procedures are in place to comply with applicable regulations and guidelines, United Therapeutics SOPs, and study requirements.

Key Accountabilities / Responsibilities

- Manage and assist in implementing and maintaining a comprehensive risk-based GVP/GCP compliant quality program
- Assist in setting annual audit schedule and preparing necessary budget
- Manage and conduct external site, vendor, and commercial partner audits according to United Therapeutics SOPs.
- Review and approve audit responses and evaluate adequacy of corrective and/or preventative actions
- Support global regulatory agency inspections and other audits of RTP and EU offices
- Identify and assist in developing standard operating procedures (SOPs) and systems needed to comply with regulatory requirements
- Manage and conduct internal clinical process audits according to United Therapeutics SOPs
- Perform quality reviews of clinical study reports and supplemental study documentation as needed
- Provide audit reports to system/process owners and Quality System Management
- Perform document record review including; general study files and site specific study files in area of responsibilities
- Provide summary reports to management of audit activities
- Assist in the coordination and conduct of functional area/departmental programs

Minimum Requirements

- Bachelor's degree in a science related field
- 6+ years of relevant pharmaceutical industry experience which includes 3+ years of Pharmacovigilance/GVP auditing or operations experience or 3+ years of direct GCP auditing experience
- Knowledge of a risk-based auditing approach to assuring compliance
- Ability to provide guidance regarding global GVP/GCP compliance regulations
- Familiar with a Company Pharmacovigilance Summary Master File (PSMF) document with the ability to contribute towards required audit-related information
- Proficient with electronic systems used to manage clinical trial data or safety reporting (i.e., eTMF, EDC,, Argus, Aris G, IVRS, etc.)
- Ability to travel to/from the office to participate in internal audits, team activities, etc. Both domestic and international travel required to conduct site and vendor compliance audits. Up to 50% travel may be required

Preferred Knowledge, Skills, and Abilities

- Working knowledge of GVP/GCP regulations and guidelines and international regulatory practices
- Knowledge of QA oversight for Pharmacovigilance trials
- Experience with GVP/GCP CAPAs, trending analysis, and/or pharmacovigilance audits
- Detail oriented and commitment to seeing tasks through to completion
- Experience and comfort in working both independently and as part of a multifunctional team
- Ability to write comprehensive audit reports and summary documentation for senior management and functional areas responsible for supporting
- Proven organizational skills and strong ability to prioritize workload
- Ability to handle high workloads, stressful situations, and deadlines

Please contact:

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