Associate Director/Director

Trevi Therapeutics is looking for a highly motivated and experienced professional **Associate Director/ Director, Quality Assurance and Compliance** to join our growing team!

Trevi Therapeutics is a late-stage biotech Company based in New Haven, CT. As we move through our lead indication trials, our Phase 2b/3 trial for pruritus in patients with prurigo nodularis and our Phase 2 trial for chronic cough in patients with idiopathic pulmonary fibrosis, we are expanding our team of highly skilled, quality focused, innovative professionals to help us achieve our goals. This is a great opportunity for professional development and to take that next step up in your career progression as you grow with the Company.

The Associate Director/ Director, Quality Assurance and Compliance can work with flexibility in either New Haven, CT or remotely to help support our Quality team.

In the role of AD/Director Quality Assurance and Compliance, you will be an important member of the Trevi Quality Team and be responsible for the following:

- Support the VP, Quality Assurance and Compliance with the development and maintenance of Quality programs, systems and processes to ensure compliance.
- Oversight and management of company Controlled Documents system (Standard Operating Procedures SOP, Guidelines, and Policies).
- Plan and lead internal and external audits, including clinical investigator sites, vendors, CMOs and CROs to assess quality and compliance.
- Communicates audit findings to stakeholders and ensures appropriate follow-up and issue resolution.
- Keeps abreast of Regulatory procedures and ensures the development and implementation of SOPs to maintain compliance.
- Manage the life cycle of vendor qualification, comprised of initial vendor qualification, quality agreements and re-qualifications, maintaining an approved supplier/service provider list.
- Initiate and review investigations, risk assessments, deviations, CAPA, change records, etc. and recommend corrective actions/CAPAs.
- Internal trend analysis of observations (audit, deviations, CAPAs); identifies and communicates all compliance risks to VP, Quality and Compliance.
- Perform root-cause analysis and other problem solving activities to identify effective corrective actions and process improvements.
- Proactively provides GCP support to Research & Development and other departments based on analysis and interpretation of updates to regulations.
- Establishes appropriate training curricula and matrices, including annual GCP trainings.

Qualifications:

- BS in a scientific discipline and a minimum of 8 years (Associate Director level) and 12 years (Director level) of related experience or a minimum of 10 years combined education/training and experience in a GCP setting for all phases of clinical trials in biotech or pharma.
- Experience & regulatory expertise of industry quality systems/standards.

- Thorough understanding of Good Clinical Practices (GCP) and global regulatory standards, guidelines, and guidance.
- Experience auditing GxP vendors who provide clinical trial and non-clinical study services, internal processes and documents, and clinical investigator sites.
- Regulatory experience a plus.
- Working knowledge of quality risk management concepts.
- Strong leadership and management skills with a good ability to collaboratively ensure all policies and procedures are being followed within the company.

Our Company offers a very lively, highly team-oriented office environment. We also provide a competitive benefits package, including excellent health insurance options, a 401(k) savings plan with a Company paid match, Company paid parking, an employer stock purchase plan and an assortment of other benefit options. The Company also believes in incentivizing its employees with annual bonus eligibility and the potential for annual stock option grants. In addition, this position offers a substantial professional growth opportunity as the Company expands its clinical development pipeline and prepares for various financing transactions and commercialization of the Company's products under development.

If interested in this unique career opportunity, please forward your resume to HR@TreviTherapeutics.com for consideration.