



## **Director, Quality Assurance**

Synthorx is a biopharmaceutical company dedicated to delivering new biologic medicines to patients suffering from cancer and autoimmune disorders. Synthorx is applying a revolutionary synthetic biology technology based on an expanded DNA code to create designer protein-based medicines.

We are hiring a driven, resourceful, and collaborative Director, Quality Assurance to join our team. The Director, Quality Assurance will be responsible for directing and implementing Synthorx's quality function, as well as planning quality policies, programs, and initiatives. The Director, Quality Assurance will also focus on GMP clinical and commercial manufacturing and clinical trial functions.

### **Key Responsibilities**

- Implement and update, as applicable, the Synthorx QMS, ensuring the system complies with applicable regulatory requirements.
- Responsible for supporting and overseeing a document control system, including document review, approval, and release, and archiving activities.
- Maintain company training records.
- Assist in ensuring the company maintains its compliance with GLP, GCP, and GMP.
- Manage the audit program.
- Assist in managing the stability programs for drug substance and drug product.
- Assist in managing compliance to CLIA and CAP laboratory requirements.
- Liaise with company personnel to ensure a full understanding of quality/regulatory requirements.
- Participate in project team meetings as quality representative.
- Provide quality oversight of contract service providers.
- Interact with external regulatory support as required.

### **Required Qualifications**

- 8+ years industry experience in quality-related position.
- BS degree in relevant field.
- Requires extensive experience and track record of judgment, project planning, and accomplishing goals within a regulatory framework.
- Has experience implementing and maintaining all aspects of a Quality Management System (QMS) for clinical and commercial drug products.
- Experience with biologics and companion diagnostics.
- Demonstrated ability to handle high volumes of work in a fluid, dynamic, stressful and fast-paced environment
- Demonstrated ability to work simultaneously on multiple projects, and to deliver high-quality work according to tight timelines
- Demonstrates excellent communication (verbal/written/presentation) skills
- Detail-oriented with effective problem-solving and troubleshooting skills
- Potential for travel (US and International)