POSITION SUMMARY

Position Title: Sr. Manager/Assoc. Director, QA

Reports to: Executive Dir., QA & Compliance

Department: QA & Compliance

Status: Regular, Full-Time, Exempt

Summary: Sunesis is a clinical-stage biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers. The incumbent for this position will independently perform a wide variety of activities to ensure compliance with applicable quality objectives and regulatory requirements for parenteral drug products. This role will have an important focus on ensuring GXP compliance with an emphasis on GCP compliance and will help drive and implement the Company’s compliance directives and supporting quality management systems to ensure compliance. This position will conduct and/or participate in GCP QA audit programs which includes both internal and external GXP audits, and will provide day to day support to the Executive Director Quality Assurance and Compliance to manage CMOs, CROs, investigator sites, relevant vendors, etc.

Specific responsibilities include, but are not limited to:

- Writing and/or implementing changes to controlled documents (e.g., SOPs, specifications, methods, etc.) as needed to ensure defined quality objectives are met.
- Maintaining document control program.
- Implementing and maintaining programs and processes to ensure compliance with current Good Clinical Practices (GCPs), Good Manufacturing Practice (GMPs) Good Laboratory Practices (GLPs) and current industry practice.
- Working with and qualification of GCP vendors.
- Providing QA support and oversight to ensure compliance with Good Clinical Practice (GCP).
- Ensuring all clinical trials are assessed for compliance with SOPs, FDA and other applicable regulations, and ICH/GCP guidelines.
- Participating in and support all GCP QA internal and external vendor management programs.
- Participating in ensuring compliance with external SOPs, e.g. CAPA, deviations, OOS, etc.
• Interfacing with CMOs/CROs to address documentation and compliance issues including investigations and corrective and preventive action (CAPA) recommendations related to manufactured products.

• Preparing lot disposition reports, reviewing planned changes, deviations, analytical reports, laboratory investigations, change controls, method and process validation protocols and reports for management review.

• Working extensively with the Head of Quality to ensure that inspections and audits are conducted on a continuing basis, to enforce requirements and meet specifications. May assist or perform GxP compliance audits as required.

• Interacting with Manufacturing, Supply Chain and Regulatory Affairs personnel to ensure that commercial drug products are manufactured and tested in accordance with established procedures.

• Supporting the facilitation of all aspects of GCP regulatory inspections internally.

• Working with Research and Development during new product start-ups, and establishing key checkpoints for new products and processes.

• Adherence to the Sunesis Code of Business Conduct & Ethics

• Other duties as assigned.

Qualifications include:

• Demonstrated in-depth knowledge of Quality Systems, ICH guidelines and GPvP modules applicable to clinical and commercial stages of product development including knowledge of European regulations.

• Working knowledge of GCP (e.g. E6/E3) regulations and EU directives

• Ability to interface with other functions like manufacturing, distribution and clinical operations

• Demonstrated audit, investigation and report writing skills

• Working knowledge and expertise in manufacturing and/or testing of sterile products

• Ability to recognize deviations from accepted practice and apply knowledge of current Good Clinical Practices (CGCP) on a daily basis

• An accountable team player who is detail and quality-oriented with solid understanding of quality assurance principles, systems, methods and procedures

• Excellent verbal, written and interpersonal communication skills required

• Experience working within a virtual company environment

• Excellent attitude and strong multitasking skills

• Ability to adapt to changing priorities and timelines and work well in high pressure environments
• Possess critical thinking skills when making sound quality decisions based on risk management and available data

• 5+ years of experience in a GCP/GMP environment or related field with a BS or BA; or 4+ years of relevant experience with an MS

• Flexibility to travel approximately 30% time both domestically and internationally

To apply for this position, please reference Job Code SNSS-1617 and email resume/CV to: Elly Grimaldi elly@grimaldistaffingservices.com/650.362.3140, Direct dial (office)