Inimmune is excited to announce an opportunity for a Quality Systems Lead/Manager **position to support several projects from preclinical development through clinical evaluations.**

Duties:

- The Qualified Applicant will be responsible for providing quality oversite for Drug Development Operations at Inimmune.
- Additional responsibilities include drafting, review and approval of SOP's and performing quality reviews of batch records for clinical supplies that support Clinical Development.
- Perform or oversee analytical method development and oversee method transfer to CMO's.

Major Responsibilities:

- Provide quality oversite of the Drug Supply ensuring compliance is met.
- Perform quality check and approval of batch records and associated documentation.
- Work closely with chemists and formulations scientists to determine proper control and consistency of drug product.
- Creation, review, approval and maintenance of Standard Operating Procedures (SOP) and Working Practice Documents (WPD) for Drug Supply.
- Establishment and Oversight of Quality systems.
- Works to implement CAPAs based on QC investigation results from quality deviations.
- Management and oversight of CMO audits and contracted operations to ensure compliance and timelines of activities.
- Perform and record QC Tests to support preclinical development activities.
- Ensure proper sample chain of custody and tracking procedures are in place and adhered to
- Draft quality policies and programs and provide guidance and feedback to production
- Manage and maintain the Company's quality inspection and product release programs for raw materials, in-process materials and components, processes and drug product.
- Manage various projects at contract laboratories
- Review and approve various documents (internal and external)
- Participate in vendor and internal audits

Preferred Skills and Experience:

- 4+ years of relevant cGMP or Quality Control work experience, or relevant comparable background, and 2+ years of relevant QA experience in a pharmaceutical or Biopharma environment.
- Knowledge of cGMP standards, 21 CFR Part 11, and potentially Annex 13 requirements.
- Experience conducting quality investigations and quality control gap analysis and risk assessments.
- Experience initiating CAPAs based on QC investigations
- Knowledge of creating and maintaining Standard Operating Procedures.
- Experience in analytical method development and Quality Control for synthetic API, protein characterization, and vaccine formulations.
- Great attention to detail.
- Demonstrates strong personal ethics and responsibility to purpose.

Qualifications

- A minimum of a Bachelor of Science in Chemistry, Biology, Immunology or related field
- Minimum of 4 or more years of prior experience in quality control related functions are required; pharmaceutical experience preferred

- Excellent organizational, verbal, written communications skills
- Knowledge of C of As, label claim requirements, HPLC, microbial, endotoxin, and other QC test methods.
- A working knowledge of quality and regulatory expectations/GMP norms for different categories of products.
- Must - be familiar with chemical compositions, structure and properties of substances used in drug manufacturing

Inimmune is located in beautiful Missoula Montana where our employees enjoy a high quality of life surrounded by a wide variety of recreational opportunities. Inimmune offers a competitive compensation program including health care, dental, 401K, and an incentive award program.

Apply online at: www.Inimmune.com or email directly to HR@Inimmune.com

Leadership, Innovation, Solutions-- Inimmune Corp. is leading in the pursuit of novel immunotherapies and innovative vaccine formulations to battle the world's most pervasive diseases.

Inimmune is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, or protected Veteran status.