Clinical Chemistry Director-Laboratory for Experimental Medicine

Lilly's dedication to excellence never ends. Our values of integrity, excellence and respect for people are embedded in all that we do. This is evidenced by the work the Laboratory for Experimental Medicine (LEM) group does to ensure the integrity and safety of our research efforts.

Lilly is looking for a LEM-Clinical Advisory Group Clinical Scientist who will provide scientific and technical leadership to the staff of the Laboratory for Experimental Medicine. We support the development, transfer, and validation of assays for the quantification of novel biomarkers used to facilitate the development and regulatory approval of new molecular entities. In this role, the emphasis will be on the implementation of immunogenicity and related biomarker assays to support the clinical portfolio. The LEM-CAG Clinical Scientist will also provide scientific expertise and consultative support to Program and Product Teams, internal Lilly partners, third-party organizations, regulatory agencies and external partners on medical and scientific issues concerning immunogenicity and related novel biomarkers.

Are you ready to apply your outstanding background and training and leadership skills to contribute to the discovery of groundbreaking therapies? We are looking to add to our dynamic and diverse team of scientists. Consider applying and joining the Lilly family today!

Primary Responsibilities:

- Lead immunogenicity, related biomarker activities and other clinical diagnostics in compliance with Lilly policies, local and international regulations, laws, guidance (e.g. FDA, EMA, ICH, etc.), Good Clinical Practices (GCPs) and corporate integrity agreements, as applicable.
- Actively contribute to developing novel immunogenicity solutions aligned with regulatory expectations.
- Provide technical oversight of third-party organizations (TPO) throughout the transfer, validation and implementation of diagnostic assays used in human clinical trials.
- Contribute in governance of Lilly relationship with TPOs including management of the vendor quality system agreement, master service agreement, periodic inspections/audits and annual governance review.
- Lead and collaborate with clinical teams to identify, develop and implement strategies to fully characterize, minimize and monitor the impact of immunogenicity on clinical outcome (benefit and risk) for patients treated with a Lilly biologic; provide data analysis and interpretation relevant to these strategies.
- Define regulatory-compliant clinical immunogenicity assessment strategies for drug candidates and guide implementation throughout development including managing all immunogenicity-related clinical and regulatory documentation support.
- Develop and deliver immunogenicity-focused regulatory submission strategies for Lilly assets including contribution in all immunogenicity-related regulatory interactions.
- Coordinate consultative and collaborative activities extending to (1) Global Patient Safety (GPS) including service on key LRL safety committees, (2) Clinical Pharmacology/Exploratory Medicine, (3) ADME-Toxicology-PKPD, and (4) other functional areas dependent upon expertise.
- Advise and influence discovery/preclinical teams regarding clinically meaningful translational opportunities.
- Maintain and expand an active external focus that includes interaction with relevant regulatory agencies as well as deliver scientific presentations and publications that will demonstrate deep scientific rigor around Lilly's approaches to immunogenicity.
Contribute to Lilly’s in-licensing efforts of new molecules and the development of strategic collaborations.

Engage in continued training and educational efforts in clinical development and demand realization related to processes requiring laboratory medicine expertise (including investigator start-up meetings, IRB, research organizations, research cooperative groups, regional business unit staff, regulatory reviews, and collaboration development efforts).

Actively set and meet professional development goals and contribute to the development of others by being an active source of mentoring and feedback.

Actively engage in recruitment, diversity, and retention efforts.

Contribute in committees, initiatives and task forces as requested by management.

Model the Lilly leadership behaviors and be an ambassador of both patients and the Lilly Brand.

**Minimum Requirements:**

- PhD, DVM, or PharmD degree in health, medical or scientific area and a minimum of 2 years of clinical or pharmaceutical experience that includes 1+ years of clinical development training and experience or training in clinical pathology/laboratory medicine, immunology/immunogenicity, or similar field.

**Additional Preferences:**

- Professional certification from the American Board of Clinical Chemistry (ABCC) or other Certification Board for Laboratory Directors of High Complexity Testing as outlined on CMS.gov (Certification Boards for Laboratory Directors of High Complexity Testing | CMS).
- Experience in analytical methodologies and clinical diagnostics.
- Ability to investigate innovative analytical technologies.
- Knowledge of regulatory requirements for clinical biomarker and clinical immunogenicity assessment and method validation/performance (e.g., GLP, CAP, NCCLS).
- Excellent problem-solving ability.
- Proven leadership and organizational skills, including positive relationship building skills.
- Excellent oral and written communication skills.
- Ability to influence and mentor others.
- Familiarity with the design and conduct of clinical trials.
- Demonstrated experience with experimental design, scientific approach to problem solving, bioanalytical method development, validation and laboratory management.
- Experience working in a regulated (e.g., GLP, GCP, GMP, CAP, CLIA, etc.) environment.
- Formal clinical training or experience in pathology and laboratory medicine.

To apply for this position, follow this link: [https://e.lilly/3Uj95ow](https://e.lilly/3Uj95ow)