Title	Clinical Chemist, Laboratory for Experimental Medicine
City	Indianapolis
State / Province	Indiana
Country	USA
Workplace Arrangement	Local
Company Overview	At Lilly, we unite caring with discovery to make life better for people around the world. We are a global healthcare leader headquartered in Indianapolis, Indiana. Our 39,000 employees around the world work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to our communities through philanthropy and volunteerism. We give our best effort to our work, and we put people first. We're looking for people who are determined to make life better for people around the world.
Responsibilities	The proportion of biomolecules in Lilly's portfolio has grown substantially over recent years and now represents at least 50% of the overall portfolio. With this increase of biomolecules in the pipeline, capabilities and processes need to be better coordinated and/or developed to meet immunogenicity requirements across our portfolio. LRL needs to ensure we efficiently meet immunogenicity requirements internally and in the external environment (e.g. regulatory) while at the same time supporting the priorities of cross functional molecule teams. The LEM (Laboratory for Experimental Medicine) Clinician-Scientist role supporting Immunogenicity is a key role that will partner closely with Exploratory Medicine/Clinical Pharmacology Organization to deliver expertise in immunogenicity and its important application in the research and development of biomolecules. This LEM Clinician-Scientist will be responsible to develop and implement immunogenicity strategies that support both early and late phase development of Lilly's portfolio. The LEM Clinician-Scientist in immunogenicity is aware of and ensures that all activities of the team are in compliance with current local and international regulations, laws, guidance (e.g. FDA, ICH, etc.), Good Clinical Practices (GCPs), corporate integrity agreements as applicable, company standards, CIA agreement, Lilly policies and procedures, and the Principles of Medical Research and are aligned with the medical vision. The primary role for this position will be to enable the strategic intent of the assessment of immunogenicity for Lilly's biologics portfolio to fully characterize, minimize and monitor the impact of immunogenicity on clinical outcome (benefit and risk) for patients treated with a Lilly biologic. These efforts will comply with all global regulatory requirements necessary to support successful pipeline progression, submission, regulatory review and approval of Lilly biologics (where appropriate), without delaying timelines. In addition the LEM Clinician-Scientist will use the knowledge gained from the assessment of immunogenicity to inform the design and selection of future biologic molecules. Core Job Responsibilities The core job responsibilities may include those listed below as deemed appropriate by line management, as well as other duties as assigned.

- LEM Clinician-Scientists manage immunogenicity activities 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.
- LEM Clinician-Scientists will provide technical oversight of third party organizations throughout the transfer, validation and implementation of LEM diagnostic assays used in human clinical trials.
- LEM Clinician-Scientists consultative and collaborative activities extend to (1) Global Patient Safety (GPS) including service on key LRL safety committees, (2) Clinical Pharmacology, (3) Biopharmaceutics and (4) other functional areas dependent upon expertise.
- In addition to the clinical responsibilities described above, LEM Clinician-Scientists also advise and influence discovery/preclinical teams regarding clinically meaningful translational opportunities.
- LEM Clinician-Scientists partner 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 and to provide data analysis and interpretation relevant to these strategies.
- The LEM Clinician-Scientists will be expected to maintain and expand an active external focus that includes interaction with relevant regulatory agencies as well as scientific presentations and publications that will demonstrate deep scientific rigor around Lilly's approaches to immunogenicity

Other LRL Consultation/Support and Responsibilities

- Participate in in-licensing efforts of new molecules and the development of strategic partnerships.
- Participate in continued training and educational efforts in clinical development and demand realization relating to processes requiring laboratory medicine expertise (including investigator start-up meetings, IRB, research organizations, Research Cooperative Groups, regional business unit staff, Regulatory reviews, and partnership development efforts).
- Actively set and meet individual professional development goals and contribute to the development of others by being an active source of coaching and feedback to co-workers
- Actively participate in recruitment, diversity, and retention efforts
- Participate in committees, Six Sigma initiatives and task forces as requested by local/corporate management
- Model the leadership behaviors
- Be an ambassador of both patients and the Lilly Brand

Basic Qualifications

- Ph.D. with certification in Clinical Chemistry from the American Board of Clinical Chemistry

Additional

- Fluent in English; both written and verbal communications

Skills/Preferences	• Demonstrated experience with strong Interpersonal, organizational, teamwork, and negotiation skills • Demonstrated ability to influence others (both cross-functionally and within the function) in order to create a positive working environment. • At least 2 years of demonstrated clinical laboratory, clinical research, drug development or pharmaceutical medicine experience or the equivalent in terms of academic experience
Additional Information	Ability to engage in domestic and international travel to the degree appropriate to support the business of the team. As part of its core mission, the Laboratory for Experimental Medicine at Eli Lilly & Co develops and clinically validates 30+ novel biomarker/immunogenicity assays annually and subsequently manages their externalization into vendor laboratories to generate GLP-like results for clinical trials. It is a nuts-to-bolts organization including state-of-the-art facilities for antibody generation and characterization, protein mass spectrometry, and assay development using a variety of spectrophotometric and biosensor platforms. In order to properly integrate LEM's functions with clinical drug development programs, a "LEM Clinician-Scientists" group was recently created, for which we are actively recruiting. Lilly is an EEO/Affirmative Action Employer and does not discriminate on the basis of age, race, color, religion, gender, sexual orientation, gender identity, gender expression, national origin, protected veteran status, disability or any other legally protected status.
Removal Date	06-Jan-2017

Additional details regarding the position can be found at https://bit.ly/29260BR_LEM