

**Title: Associate Medical Advisor****Indianapolis, IN**

Requisition ID: 24889BR

We have a newly created position within the Laboratory for Experimental Medicine (LEM), part of the Tailored Therapeutics (TTx) division at Eli Lilly & Co, seeking a board-certified/eligible MD (or DO) with laboratory medicine experience/expertise. Titled the “TTx-LEM Physician-Scientist”, 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 TTx-LEM Physician-Scientist will use the knowledge gained from the assessment of immunogenicity to inform the design and selection of future biologic molecules.

As part of its core mission, the TTx division at Lilly supports clinical drug development through its diverse functions including oversight of therapeutic tailoring strategies, characterization of human disease heterogeneity, drug target validation, and the development and clinical implementation of novel biomarkers to monitor drug safety, target engagement and pharmacodynamic effect. TTx has a long history of recruiting anatomical and clinical pathology-trained physician/scientists and positioning them within key roles to support clinical programs within Eli Lilly. Within TTx, the LEM was originally built and is currently lead by a U Penn-trained Clinical Pathologist, who previously served as faculty in the Dept. of Pathology at UAB and Clinical Chemistry Director until he joined Eli Lilly in 2001, where he is currently appointed as a Distinguished Medical Fellow. The LEM 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 “TTx-LEM Physician/Scientist” group was recently created, including the open position described here. The TTx-LEM Physician/Scientist role supporting Immunogenicity will also partner closely with the Exploratory Medicine/Clinical Pharmacology division to deliver expertise in immunogenicity and it’s important application in the research and development of biomolecules. This group will be responsible for working with clinical teams to develop and implement immunogenicity strategies that support both early and late phase development of Lilly’s portfolio.

**BASIC QUALIFICATIONS**

- Medical Doctor or Doctor of Osteopathy. Must be board eligible or certified in appropriate specialty/subspecialty (including ABCC or equivalent) US trained physicians must have achieved board eligibility or certification. Foreign medical graduates (in US based jobs) who are not US board eligible or certified may be hired directly for employment in the US at the discretion of the Chief Medical Officer.
- Non-US trained physicians must have completed education and training at a medical school that meets the requirements of the Liaison Committee on Medical Education (LCME). For the recognized list of foreign medical schools and the disapproved list, see <http://www.in.gov/pla/2799.htm>
- Fluent in English; both written and verbal communication

**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

### **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.

Immunogenicity Physicians/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.

- In addition to directly partnering with the clinical teams, Immunogenicity Physician/ 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, Immunogenicity Physicians also advise and influence discovery/preclinical teams regarding clinically meaningful translational opportunities.
- Immunogenicity Physicians/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 TTx-LEM physician scientist 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.

### **ABOUT LILLY**

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.

Additional details regarding the position can be found at [http://bit.ly/24889\\_Lilly](http://bit.ly/24889_Lilly) or please refer any potential candidates to the Lilly Careers Page – Reference #24889 (or the Lilly recruiter, Liberty Wilken: [Wilken\\_liberty@lilly.com](mailto:Wilken_liberty@lilly.com)) and/or the hyperlink.