The Ahmanson Division of Translational Imaging (ATID), Department of Molecular and Medical Pharmacology, David Geffen School of Medicine at UCLA, is recruiting a non-tenure track, full-time Adjunct faculty position at the Assistant Professor level to serve as Director of Regulatory Affairs and Science. The anticipated start date is July 1, 2019.

The ATID has created a successful translational science program, ranging from biology, chemistry/radiochemistry, PET probe development, drug development, and preclinical imaging to clinical research and clinical service. Among its more recent accomplishments is the establishment of the premier translational theranostic program in the nation.

To meet the Division’s distinct and growing needs, this position will be responsible for five general areas: regulatory science (including strategic planning, preapproval, approval, and postapproval), animal GLP safety pharmacology and toxicology research, biomedical cyclotron facility GMP compliance, nuclear medicine clinical GCP compliance, and teaching and training. Responsibilities include, but are not limited to, the following:

**Regulatory Science**
- Strategic planning - oversee the regulatory framework, determine regulatory pathways and options, and interact with industry and other academia
- Preapproval – oversee all aspects of nonclinical and clinical development, CMC and manufacturing, and FDA interaction
- Approval – manage all regulatory and administrative, nonclinical and clinical, CMC and manufacturing aspects, and the submission and review process
- Postapproval – manage postmarketing/maintenance, postmarketing surveillance/vigilance, advertising, promotion, labeling, distribution, and FDA interaction

**Animal GLP Pharmacology and Toxicology Research**
- Provide leadership and direction to the ATID for human use enabling animal safety pharmacology and toxicology research
- Strategically plan, direct and manage GLP animal safety pharmacology study and toxicology studies
- Negotiate and liaise with preclinical animal study Contract Research Organizations (CROs)

**Biomedical Cyclotron Facility GMP Compliance**
- Oversee and manage the planning, implementation and maintenance of the quality assurance (cGMP) program at the Biomedical Cyclotron, an FDA-registered drug manufacturing facility

**Nuclear Medicine Clinic GCP Compliance**
- Direct and manage nuclear medicine quality assurance program for Good Clinical Practice regulatory compliance

**Teaching and Training**
- Provide regulatory lectures to graduate students
- Train nuclear medicine staff and investigators in ICH E6 GCP compliance, and fundamentals of radiopharmaceutical US regulations and regulatory pathways
- Train biomedical cyclotron cGMP staff for radiopharmaceutical cGMP requirements and compliance, regulatory policies and procedures

Candidates must have a degree in Regulatory Science or a related field and possession of Regulatory Affair Certification by RAPS is required. The candidate must have documented experience with
Investigational New Drug Applications, New Drug Applications (NDA and ANDA), and a track record of interacting with and submitting applications to institutional ethics committees.

Candidate must also document ability to:
- evaluate proposed investigational products for regulatory classification (PET drug, therapeutic radiopharmaceuticals, etc) and jurisdiction;
- monitor and assess the regulatory environment for product specific guidances, competitor products etc. to propose regulatory pathways such as 505b1 505b2 NDA, 505j ANDA with paragraph certification, exploratory, traditional, single-patient emergency, single patient non-emergency, intermediate-size population, treatment INDs;
- evaluate US regulatory implications for non-US (mostly European) development and determine the non-US data utility in supporting US drug development and regulatory submission;
- provide input to FDA and nuclear medicine community (SNMMI meetings, etc.) to influence regulatory environment (legislation, regulation, guidance documents); publish peer-reviewed articles to share regulatory and compliance experiences and opinions to influence regulatory environment;
- conduct regulatory due diligence and advise head of nuclear medicine of regulatory implications and risk/benefit assessment for projects collaborated with industry or other academia;
- develop preclinical safety, pharmacology and toxicology studies for first in human enabling studies.

Interested applicants should submit a cover letter summarizing professional experience, a curriculum vitae, and arrange for three letters of reference to be submitted to UC Recruit: https://recruit.apo.ucla.edu/JPF04348

The University of California is an Equal Opportunity/Affirmative Action Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, age or protected veteran status. For the complete University of California nondiscrimination and affirmative action policy see: UC Nondiscrimination & Affirmative Action Policy

We welcome candidates whose experience in teaching, research, or community service has prepared them to contribute to our commitment to diversity and excellence.