Opportunity Title: Patch Clamp Studies for Cardiac Safety Evaluation Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2019-0351

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2019-0351

How to Apply A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional references

All documents must be in English or include an official English translation.

If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Description An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland.

The FDA has an ORISE fellowship opportunity for an in vitro electrophysiology candidate to participate in research that addresses mechanisms of drug action, including opioids, related to ion channels and excitable cells. This position is located in the Division of Applied Regulatory Science (DARS) / Office of Clinical Pharmacology (OCP), and represents an excellent opportunity to learn about and contribute to applied regulatory research experiments that have an immediate impact on human health.

This research fellow will be a part of a highly collaborative team, and will participate in a range of ongoing and emerging research projects. An ongoing research project is cardiac ion channel pharmacology experiments to support the “Comprehensive In vitro Proarrhythmia Assay” (CiPA) initiative. CiPA is a global collaboration amongst regulatory, industry, and academic scientists to develop a new in vitro / in silico paradigm for assessing drug-induced proarrhythmia risk.

Under the guidance of a mentor the participant will examine effects of drugs with defined clinical risk in addition to opioid receptor agonists and antagonists on several human cardiac ion channels using whole cell patch clamp method and recombinant cell lines. These electrophysiology data will be integrated into a computer model of the human ventricular myocyte to predict the level of drug-induced proarrhythmia risk. To learn more about CiPA, see http://www.cardiac-safety.org/2018/05/new-advances-in-the-assessment-of-drug-induced-arrhythmias-and-the-comprehensive-in-vitro-proarrhythmia-assay-cipa/. As needed to verify model output, the fellow will conduct current clamp experiments to examine drug effects on action potentials generated by cardiomyocytes. Emerging research projects typically address drug safety issues that surfaced post-market. An example of this kind of project is addressing mechanisms of cardiac toxicity associated with abuse and misuse of loperamide, an over the counter opioid receptor agonist (https://www.ncbi.nlm.nih.gov/pubmed/28830713).

By participating in mission-critical research assignments at the FDA, the fellow will learn about the systems approach taken by the DARS/FDA to determine drug safety and efficacy, and how translational research is designed here that incorporates state-of-science information to yield solutions that immediately impacts human health.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an

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interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

Qualifications

The qualified candidate must have received a doctoral degree in Biophysics, Neurosciences, Biomedical Engineering, Systems Biology, Pharmacology, Physiology or related fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Solid understanding of the principles that govern excitable cell and ion channel functions
- Familiarity with ion channel properties and pharmacology
- Experience utilizing patch-clamp methods in current and voltage clamp configurations to evaluate the ionic mechanisms underlying cardiac action potentials and predict proarrhythmia propensity of drugs in the context of normal and disease states
- Experience analyzing and interpreting complex electrophysiology dataset to deduce mechanisms of drug actions and drugs' proarrhythmia propensity in the context of normal and pathophysiological states.
- Ability to prepare acutely dissociated cardia myocytes, using Igor Pro and writing macros

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (5 👁)
  - **Mathematics and Statistics** (2 👁)