Advanced In Vitro Modeling Fellowship
Division of Applied Regulatory Science
Office of Clinical Pharmacology
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Silver Spring, MD

FDA-CDER-2014-0043

Project Description:

A fellowship opportunity is currently available in the Division of Applied Regulatory Science (DARS) within the Office of Clinical Pharmacology (OCP) at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA).

OCP's mission is to assure the safety and effectiveness of new drugs through the evaluation of clinical pharmacology and biopharmaceutics data in support of CDER's Investigational New Drug (IND), New Drug Application (NDA), and Biologics License Application (BLA) review programs.

The objectives of this project are to utilize advanced *in vitro* methods to address specific regulatory research issues. The methods may include using human or rodent primary or continuous cell lines. In addition, using genetically modified cell lines or using defined cell types derived from stem cells may be indicated. The developed *in vitro* methods may be used in collaborative studies in conjunction with *in vivo* models to specifically address questions related to the predictive power of the *in vitro* models.

Additionally, the project may compare the responses of pure monotypic cell populations with those of defined, but mixed, cell populations to more clearly understand the role of intercellular communication in toxicological or pharmacological responses.

The Research Participation Program for FDA is administered by the Oak Ridge Institute for Science and Education (ORISE). 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 depending on educational level and experience. The participant must show proof of health insurance. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications:

- A Doctoral degree in cell biology, physiology, biophysics, biochemistry, or immunology received within the last five years. Other related fields with research experience focused on the development of in vitro methods will be considered.
- Experience with a variety of cell culture models (i.e., continuous and/or primary cell cultures) and with multiple readout systems (i.e., absorbance, fluorescence or physiological methods) is necessary.
- Experience in developing a mature cell culture from a stem cell source and a history of publication in peer-reviewed scientific journals is desired.
- Experience in producing cell lines with specific genes knocked in or out, with drug pharmacology or toxicology studies, and with basic methods for measuring drug concentrations (e.g., HPLC) is beneficial.
- US Citizenship or Legal Permanent Resident status required.

How to Apply:
To be considered, please send a current CV/resume to the attention of OTSORISE@fda.hhs.gov . Please reference **FDA-CDER-2014-0043** in all communication