Metabolism and Toxicology 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-2014-0035

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, New Drug Application, and Biologic License Application review programs. Under the guidance of a mentor, the selected participant will develop and assess MS-based analytical methods for metabolism and toxicology studies. S/he will also research into methods for efficient and reproducible sample preparation, focusing on the validation of quantification methods used for measuring drugs and their metabolites. S/he will primarily use a Thermo TSQ Quantum AM for this research.
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 chemistry or biochemistry with an emphasis on the use of mass spectrometry as an analytical tool for studying small molecule drugs received within the last five years.
- Familiarity with Xcalibur is highly desired; working knowledge of DBA is preferred.
- Experience with DMPK studies and with PK/PD modeling is beneficial.

How to Apply:
To be considered, please send a current CV/resume to the attention of OTSORISE@fda.hhs.gov. Please reference **FDA-CDER-2014-0035** in all communications.