



Opportunity Title: Bioinformatics Fellowship - FDA CDER


Opportunity Reference Code: FDA-CDER-2019-0379



Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2019-0379
How to Apply	<p>A complete application consists of:</p> <ul style="list-style-type: none"> • 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 <p>All documents must be in English or include an official English translation.</p> <p>If you have questions, send an email to ORISE.FDA.CDER@orau.org. Please include the reference code for this opportunity in your email.</p>
Description	<p>An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland.</p> <p>This project located in the Office of Translational Science (OTS) Office of Clinical Pharmacology (OCP) will develop and validate animal models that can improve FDA's ability to predict and characterize potential clinical issues in metabolism, safety and product quality using animal models prior to human testing.</p> <p>Under the direction and guidance of a mentor, the participant will have the opportunity to learn how to use advanced genomics and other -omics or big data technology, such as next generation sequencing (NGS) and cutting-edge bioinformatics methods, to evaluate a drug's therapeutic efficacy and/or safety, and apply this data mining/machine learning approach to decision making during drug development or regulatory assessment.</p> <p>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 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.</p> <p>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.</p> <p>FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:</p> <ul style="list-style-type: none"> • Non-employee nature of the ORISE appointment;



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- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate must have received a master's or doctoral degree in life, or medical health sciences, or bioinformatics or a related field. Degree must have been received within five years of the appointment start date.

Familiarity with big data technologies is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
 - **Environmental and Marine Sciences** (1 )
 - **Life Health and Medical Sciences** (45 )