Opportunity Title: FDA Methods for Therapeutic Equivalence Assessment Fellowship
Opportunity Reference Code: FDA-CDER-2020-0574

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

Reference Code FDA-CDER-2020-0574

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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
- One educational or professional recommendation

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

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

Application Deadline 3/31/2021 2:55:16 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

Five research opportunities are currently available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD) located in Silver Spring, Maryland.

The Office of Generic Drugs (OGD) coordinates and manages the generic product review process, provides safety, surveillance, clinical, and bioequivalence reviews for generic products, as well as develops policy and regulatory science research to assist in evaluation of generic drugs and their approval. To lead these regulatory science commitments, the Office of Research and Standards (ORS) was formed in 2014. The Division of Therapeutic Performance (DTP), one of the two divisions within ORS, consists of subject matter experts with diverse backgrounds who conduct and promote regulatory science research to establish standards in order to ensure therapeutic equivalence of generic versions of drug products. The division also facilitates pre-ANDA development of generic drugs, using various tools such as product specific recommendations, guidance development, and direct communications with generic sponsors, such as through controlled correspondences, and pre-ANDA meeting requests.

This project at DTP will provide the participant with the opportunity to acquire keen understanding of regulatory science that supports the development of therapeutic equivalence assessment standards.
This project will offer early career scientists unique opportunities to broaden their regulatory science knowledge by learning from experienced scientific reviewers within DTP and across other offices at CDER, and with extramural collaborators.

Under the guidance of a mentor, the participant may be trained in the

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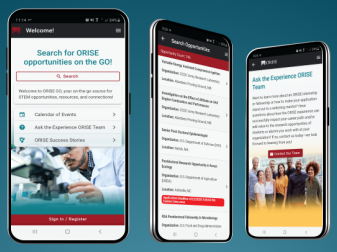
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following activities:

- Intramural and extramural research studies; to develop new bioequivalence (BE) methods and pathways for locally acting drugs for inhalation, topical dermatological, nasal, GI acting, ophthalmic, and otic products
- Establishment of BE assessment methods and standards for complex products such as liposomes, sustained release parenterals, and complex mixtures
- Investigation of patient use factors such as tablet size, and device design for their impact on generic substitutability
- Investigate feasibility and value of in vivo predictive dissolution methods for solid oral dosage forms through establishing in vitro-in vivo correlations
- Identify analytical methods to characterize peptides and other complex mixtures and particle size and surface chemistry for potential generic products
- Utilize large, pooled clinical trial datasets to identify potential pharmacodynamic marker/clinical endpoints for BE assessment of locally acting drugs
- Examine emerging novel formulation technologies to identify key areas for future OGD regulatory science research
- Evaluate the role of excipients on product performance and bioavailability
- Investigate feasibility and value of using emerging and improved in vitro technologies for evaluating generic product equivalence and evaluate whether these technologies should replace existing methods
- Identify novel tools to detect and measure the physical structure, chemical properties, and particle size to assess performance of products containing nanoparticles, liposomes, microspheres
- To identify, improve and standardize science-based in vitro approaches for BE assessment of drug-device combination products such as inhalation, nasal and auto-injectors
- Optimize comparative clinical trial design and statistical methods of analysis to address issues such as missing data, multiple endpoints, patient enrichment, and adaptive designs
- Identify and evaluate related biomarkers for pharmacodynamic BE trials in areas where optimal endpoints are lacking
- Develop product specific and general guidance on BE assessment of generic products

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

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program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

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:

- Non-employee nature of the ORISE appointment;
- 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 should have received a doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)