Opportunity Title: Methods for Therapeutic Equivalence Assessment Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2018-0251

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

Reference Code FDA-CDER-2018-0251

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 A research opportunity is available in the Office of Generic Drugs at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

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, 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 position 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 fellowship 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.

The participants may be trained in the 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

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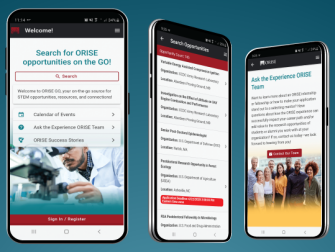
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complex mixtures.
- Investigation of patient use factors such as tablet size, and device design for their impact on generic substitutability.
- Investigate feasibility and value of in vivo predictive dissolution methods for solid oral dosage forms 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 standardized 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 12 months, 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, MD area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications A doctoral, medical, PharmD, or other qualified scientists holding advanced degree(s) in Clinical Pharmacology, Pharmaceutical Sciences, Chemistry, or Engineering received within the last 5 years.

Eligibility
- **Degree:** Doctoral Degree received within the last 60 month(s).

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Requirements

- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)