Opportunity Title: Botanical Review Team Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2017-0061

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

Reference Code FDA-CDER-2017-0061

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 at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER).

Establishing adequate quality standards, identification of critical attributes of drug substance and formulation, critical process parameters and their interactions, and development of control strategy is one of the main challenges in new drug and biologics (containing complex drug substances/complex dosage forms) regulation. Addressing these issues requires comprehensive product and process understanding of these drug products to support guidance and policy development needed for ensuring availability of high quality new drugs and biologics.

With the support of a mentor, the participant may engage in:

- Updating botanical database including marijuana database.
- Reviewing literatures for specific botanicals of interest, i.e. conduct data searches in published literature, FDA databases, and other regulatory publications to collect quality data for new drugs.
- Performing literature searches for chemical fingerprint and bioassay in quality control for botanical drugs.
- Identifying a series of critical quality attributes and developing test procedures and acceptance criteria based on these attributes.
- Identifying critical formulation and manufacturing process variables affecting the quality of new drugs and biologics.
- Engaging with a team establishing quality standards to facilitate product development and review.

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

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Silver Spring, MD area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications

Applicants must have received a Master's, Bachelor's, or Doctoral degree in pharmaceutical sciences, biomedical sciences or related disciplines within five years of the desired starting date. Familiarity with natural or biological complex products is preferred.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or 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)