Opportunity Title: Botanical Review Team Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2019-0371

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

Reference Code FDA-CDER-2019-0371

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 An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland.

This project located in The Office of Pharmaceutical Quality (OPQ) Immediate Office (IO) Scientific Staff (SS) will establish adequate quality standards; address critical attributes of drug substance and formulation, critical process parameters and their interactions, and development of control strategy in new drug and biologics (containing complex drug substances/complex dosage forms). 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 will be trained on:

- 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
- testing 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 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.

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

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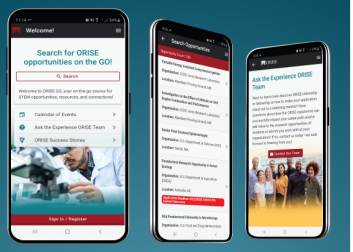
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U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

Qualifications

The qualified candidate should have received a bachelor's, master's or doctoral level degree, or are currently pursuing a master's or doctoral degree in pharmaceutical sciences, biomedical sciences, or related disciplines. Degree must have been received within five years of the appointment start date.

Familiarity with natural or biological complex products is preferred.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Life Health and Medical Sciences** (2 👁)

Affirmation

I have received a bachelor's, master's or doctoral degree within the past five years, or are currently pursuing a master's or doctoral level degree.