

Opportunity Title: Small Business and Industry Assistance Fellowship - CDER

Opportunity Reference Code: FDA-CDER-2017-0029

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

Reference Code FDA-CDER-2017-0029

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), in the Office of Communications/Division of Drug Information.

> The Center for Drug Evaluation and Research (CDER) Small Business and Industry Assistance (SBIA) promotes productive interaction with regulated domestic and international small pharmaceutical business and industry by providing timely and accurate information relating to development and regulation of human drug products. To meet such a challenge requires metrics analysis and data mining to influence CDER SBIA programs; determine efficiency; review existing and recommend new policies and procedures.

The office is seeking an individual to research existing best practices to recommend strategies to successfully implement programs and engage in educational outreach to the pharmaceutical industry and internal stakeholders to increase efficiency of CDER SBIA.

Participants may be involved in: learning about the FDA drug regulatory process first hand, including different areas of the Agency; reviewing and analyzing CDER SBIA outreach initiatives; metrics analysis and data mining to influence programs and determine efficiency; and interacting with and determining the regulatory needs of the pharmaceutical industry.

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 6 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.



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Qualifications Applicants must have received a bachelor's degree within five years of the desired starting date. Applicant should be conversant with the US pharmaceutical industry and their educational needs and practices. Strong analytical and visualization skills preferred

Eligibility • **Degree:** Bachelor's Degree received within the last 60 month(s).

Requirements

- Discipline(s):
 - Communications and Graphics Design (1...)
 - Computer, Information, and Data Sciences (4_●)
 - o Engineering (2_●)
 - Mathematics and Statistics (10 ●)

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