Opportunity Title: CDER Lean Process Improvement Initiative Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2016-0075

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

Reference Code FDA-CDER-2016-0075

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 Strategic Programs/Office of Program & Strategic Analysis at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

The CDER Lean mission is to protect the public health by supporting CDER in maximizing operational potential and achieving higher efficiencies by cultivating an environment of continuous improvement through lean management strategies. Lean Management is the pursuit of perfection along a process - a unified vision that challenges us to recognize and achieve opportunities within an organization through continuous process improvements. While lean continuous improvement originated in the manufacturing setting, these guiding principles have proven growing success in myriad industries including the healthcare and government sectors. The fellow will develop knowledge of core Continuous Process Improvement (CPI) and Lean principles and methods as well as facilitative leadership, public speaking, and project management skills through just in time training and direct application of knowledge gained at customer-facing events focused on improvement of key CDER processes. The fellow will assist in facilitating improvement efforts focused on CDER application (NDA, BLA, ANDA) review processes and associated guidances and policy.

Upon completion of this program, the participant will:
• Demonstrate knowledge of core principles and methods of lean continuous process improvement, facilitative leadership, public speaking, and project management skills.
• Be able to apply acquired skill set in any setting including the healthcare and pharmacy sectors, where optimizing flow, maximizing customer service experience, increasing efficiency, and reducing waste while eliminating errors are critical to improving public health.
• Describe several of CDER's end-to-end processes and organizational roles in each process critical to the review, approval, and postmarket surveillance of drugs.
• Be familiar with FDA laws, user fee acts, regulations, and guidance documents relevant to CDER's core review processes.

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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 or the program administrator, and there are no fringe benefits paid.

Qualifications A bachelors degree in the life, health, or medical sciences received within five years of the desired starting date.

Eligibility Requirements

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