Opportunity Title: Data Analysis Fellowship-FDA
Opportunity Reference Code: FDA-CDRH-2016-0160

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

Reference Code FDA-CDRH-2016-0160

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 currently available at the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), Office of Surveillance and Biometrics (OSB), in Silver Spring, MD.

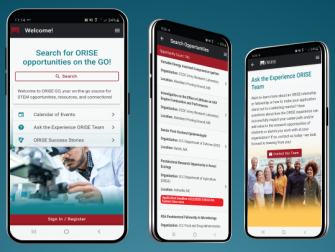
The research participant will have an oppurtunity to manipulate and analyze data, report results and provide findings related to the capture of Unique Device Identification Data across several Center data sources.

This project will initially focus on a specific Class I recall to outline the workflow and processes needed to consistently capture UDI across FDA CDRH internal systems, evaluate the current UDI data available for the identified recall, identify the processes for linking product information to GUDID and providing feedback on the usefulness of the data in GUDID for meeting the needs of the CDRH AE and recall programs. Based upon the insights gained from the initial use case the remainder of the project will examine the existing capture of UDI – DI + PI in all incoming CDRH databases, the consistency in using the DI and existing AccessGUDID APIs to auto-populate data identification fields with GUDID fields, and identifying opportunities for improving the data in GUDID to better meet the goals of the National Evaluation System. Calling upon clinical and engineering expertise within the Center to inform capture and integration of GUDID data will provide the basis for more coordinated dialog with National Evaluation System and early UDI adopter pilots. The focus on internal data capture will assist in external efforts to capture UDI in electronic health information, including hospital-based adverse event reports and software that supports the management of device recalls. The evaluation may also be used to support future development of guidance and policies related to manufacturer implementation of the UDI regulation.

Desired appointment start date is December 1, 2016, for a 9 month appointment.

The ORISE fellow may:

- Identify data completeness and accuracy and conduct research to

OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION
ORISE GO

The ORISE GO mobile app helps you stay engaged, connected and informed during your ORISE experience – from application, to offer, through your appointment and even as an ORISE alum!
Visit ORISE GO
GET IT ON Google Play
Download on the App Store

Opportunity Title: Data Analysis Fellowship-FDA
Opportunity Reference Code: FDA-CDRH-2016-0160

assist with providing recommendations on best course of action to improve the integration of UDI in CDRH data systems.
- Collaborate with data source owners to analyze and problem solve issues with current systems as they relate to the integration and management of UDI in recall and adverse event data collected by CDRH.
- Monitor for timely and accurate completion of select data elements.
- Identify, analyze, and interpret trends or patterns in complex data sets.

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 9 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, Maryland area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Qualifications

Applicants must be currently pursuing or have received a Masters or Doctoral Degree in Information Management, Healthcare Information, Computing, Mathematics, Library and Information Sciences, or related fields.

Knowledge, Skills, and Abilities

- Technical expertise regarding data models and database design development. Understanding of XML and SQL.
- Experience using Query tools and Master Data Management software packages is desirable for analyzing large datasets.
- Computer programming skills, adept at queries and report writing.
- Knowledge in using basic statistical functions and usage in data analysis.
- Experience using data mining techniques and procedures and knowing when their use is appropriate.
- Ability to present complex information in an understandable and compelling manner.
- Ability to document process flows, policies and procedures and writing skills to document and present project accomplishments, policies and procedures.

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Environmental and Marine Sciences** (1 👁)

Opportunity Title: Data Analysis Fellowship-FDA
Opportunity Reference Code: FDA-CDRH-2016-0160

- **Life Health and Medical Sciences** (45 👁)
- **Mathematics and Statistics** (3 👁)