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Opportunity Title: Digital Health Fellowship - FDA CDRH
Opportunity Reference Code: FDA-CDRH-2019-0001

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

Reference Code FDA-CDRH-2019-0001

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 Devices and Radiological Health (CDRH) in Silver Spring, Maryland.

The Software Precertification (Pre-Cert) Pilot Program, as outlined in the FDA's Digital Health Innovation Action Plan [PDF], will help inform the development of a regulatory model to assess the safety and effectiveness of software technologies without inhibiting patient access to these technologies.

The FDA envisions that the future regulatory model will provide more streamlined and efficient regulatory oversight of software-based medical devices developed by manufacturers who have demonstrated a robust culture of quality and organizational excellence, and who are committed to monitoring real-world performance of their products once they reach the U.S. market. This proposed approach aims to look first at the software developer and/or digital health technology developer, rather than primarily at the product, which is what we currently do for traditional medical devices. Because software products can be adapted to respond to glitches, adverse events, and other safety concerns quickly, the FDA is working to establish a regulatory framework that is equally responsive when issues arise to help ensure consumers continue to have access to safe and effective products. In the Pre-Cert program, the FDA is proposing that software products from precertified companies would continue to meet the same safety and effectiveness standard that the agency expects for products that have followed the traditional path to market.

The learning objectives of this training will include:

- Perform research to support the development and implementation of regulatory policy in one or more of the digital health focus areas (software lifecycle management processes - premarket and post market, mobile medical apps, medical device interoperability, healthcare cybersecurity, wireless technologies, cloud-enabled software deployment, machine learning/artificial intelligence, big data, advanced analytics, digital health product development)
- Coordinate and provide support to FDA work groups establishing digital health regulations, procedures, and programs having national or international impact
- Support the development of white papers, documents and communication strategies for CDRH's precertification program pilot
- Support the development of training on new digital health technology regulations, procedures, and programs to key stakeholder audiences
- Support the development of software application or automation tools as a proof of concept for

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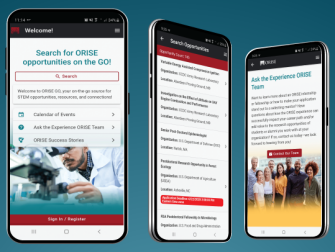

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various regulatory guidance

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 five 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.

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 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.

Desired Appointment Start Date: November 15, 2018

Qualifications

The qualified candidate should be a current student or postgraduate in data science, computer science, electrical engineering, software engineering or biomedical engineering. Degrees must have been received within five years of the appointment start date.

Familiarity with the software development life cycle is desired.

Preferred skills:

- computer programming
- knowledge of SharePoint and the Microsoft suite of tools
- knowledge of agile project management
- strong writing skills

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Engineering** (3 👁)
  - **Life Health and Medical Sciences** (1 👁)
  - **Social and Behavioral Sciences** (2 👁)

Affirmation

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