Staff Fellow Vacancy Announcement: Research Scientist

Office of Counterterrorism and Emerging Threats

The Food and Drug Administration (FDA), the Office of the Commissioner (OC), Office of the Chief Scientist (OCS), Office of Counterterrorism and Emerging Threats (OCET). The FDA is a Federal scientific law enforcement agency with the legislated responsibility to protect and promote the public health of the Nation's consumers. FDA also plays a significant role in the Nations' counterterrorism capability by ensuring security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

OCET develops and coordinates the implementation of comprehensive FDA plans and strategies for these portfolios in collaboration with FDA centers and offices, and with external U.S. government and international partners. Coordinates FDA's Medical Countermeasures Initiative (MCMi) to facilitate the development of safe and effective MCMs against chemical, biological, radiological, and nuclear agents and emerging threats, such as pandemic influenza. OCET also develops and coordinates implementation of FDA policies and procedures to facilitate the availability of MCMs, including efforts to safeguard MCMs from adulteration or disruption of supplies during public health emergencies, and enable access to available MCMs when necessary, through an appropriate mechanism, such as Emergency Use Authorization.

The Advanced Manufacturing Team is responsible for the developing and maintaining computational manufacturing models used in the OCET Advanced Manufacturing demonstration facility. Technologies such as smart manufacturing, closed loop controls, continuous cell culture, and other emerging innovations will be researched. The team will also collaborate with Center researchers to plan and conduct research, and provide technical expertise to FDA advanced manufacturing activities. Specific duties include the following:

- 1. Use scientific expertise to create demonstrations, use cases, and scenarios to investigate the utility, benefits, and challenges in implementing advanced manufacturing for a variety of medical products
- 2. Collaborate with internal and external scientists and regulators to develop research projects, collect, and analyze data that answer Center-based regulatory science, regulatory, and policy questions.
- 3. Serve as primary author on technical reports regarding research studies performed in the facility as well as assessing emerging technologies, landscape analyses, steering committee recommendations, to make recommendations for future directions, acquisitions, and needs of the Agency.
- 4. Provide demonstrations and training sessions to FDA staff and other groups organized by the OCET Advanced Manufacturing Pilot Program.
- 5. Consult with other government agencies, standards-setting organizations, and stakeholders on matters related to their area of responsibility.

Educational Experience Requirements

Applicants will be required to possess either a PhD or master's degree from in Medical or Health Sciences or combination of education and experience that meets the specific qualification requirements of the General Medical and Healthcare Series (0601) occupational series below.

Professional Experience Requirements

Applicants should have:

- Graduate or post-doctoral experience developing and leading research projects in closed loop control systems for biomanufacturing (e.g. pharmaceuticals, biopharmaceuticals, gene therapies, vaccines, or diagnostics).
- Experience validating artificial intelligence and machine learning algorithms is highly desirable.
- Experience working with highly technical interdisciplinary teams

To qualify as a Staff Fellow, you must be a US Citizen, Permanent Resident, or Non-Citizen with residency status in the U.S., three (3) out of the last five (5) years. The positions are located in Silver Spring area of Maryland. The positions will be filled through FDA's Staff Fellowship program. Appointments will be made up for up to two years with opportunities for renewal. Applicants may be required to live in, or be willing to relocate to, the greater Washington DC area. The salary range is \$74,950 to \$116,788 based on experience and education.

Please submit your letter of interest, curriculum vitae or resume, and transcripts to: OCETAdvancedManufacturing@fda.hhs.gov with the subject line of "OCET Research Engineer Staff Fellow Positions." Questions may also be directed to the OCET Advanced Manufacturing mailbox. Applications will be accepted through August 1, 2022.

CONDITIONS OF EMPLOYMENT: This position will be filled through the Service Fellowship program, with an initial appointment period followed by opportunities for renewal. **Applications will be accepted from all groups of qualified candidates, including U.S. citizens or non-U.S. Citizens holding valid immigration status and work authorization at the FDA.** No previous Federal experience is required. Appointment does not confer any entitlement to a position in the competitive service, and during the initial appointment there is no entitlement to Merit Systems Protection Board (MSPB) appeals rights.

- One-year probationary period may be required.
- Official Transcripts required.
- Background and/or Security investigation required.
- If applicant is an U.S. Citizen, males born on, or after, December 31st, 1959 must be registered with the Selective Service System or have an approved exemption. Visit www.SSS.gov for more info.
- Prohibited financial interest restrictions may apply. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at <u>FDA Ethics and</u> Integrity Office.

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^{**}Applications will be reviewed and interviews will be scheduled on a first come, first serve basis. **