Opportunity Title: FDA Fellowship in Collagen Implants
Opportunity Reference Code: FDA-CDER-2022-1205

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

Reference Code FDA-CDER-2022-1205

How to Apply

Connect with ORISE...on the GO! Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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
- One educational or professional recommendation

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 1/5/2023 3:00:00 PM Eastern Time Zone

Description

***Applications will be reviewed on a rolling-basis.**

A research opportunity is available in the Office of Testing and Research (OTR), Division of Product Quality Research (DPQR) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), located in Silver Spring, Maryland. CDER performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than just medicines.

The project is aimed to investigate the effect of various sources, manufacturing processes, and grades of collagen materials on the quality and in vitro performance of the collagen-matrix implant.

Under the guidance of the mentor, the participant will receive practical training and educational experience on the lab scale manufacturing of implant products, mitigation and process control strategies and how to utilize state-of-the-art analytical instrumentation. The participant will also gain an understanding of the current regulatory requirements and risk assessment strategies for the collagen or related implant drug products.

Anticipated Start Date: The start date is flexible and will depend upon a variety of factors.

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

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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, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate should have received a master's or doctoral degree in one of the relevant fields, or be currently pursuing the degree with completion by January 5, 2023. Degree must have been received within the past five years.

Preferred Skills:

- Strong analytical experience is preferred, as well as a background in pharmaceutical science.
- Knowledge on characterization of material/drug products, polymer chemistry or in vitro release test is desirable.
- A strong background in written and oral communication with a publication history in peer reviewed journals is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 1/5/2023 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (5 👁)
  - **Life Health and Medical Sciences** (2 👁)

Affirmation

I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)