

Opportunity Title: FDA Risk Assessment of Contaminants for Supply Chain Risks

Opportunity Reference Code: FDA-CDER-2026-0077

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

Reference Code FDA-CDER-2026-0077

How to Apply *To submit your application, scroll to the bottom of this opportunity and click 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
- 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 5/31/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available immediately with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in Silver Spring, Maryland.

The Center for Drug Evaluation and Research (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 U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This effort covers more than just medicines.

Research Project: You will participate in proactive research to identify emerging impurities and contaminant issues. Using benzene contamination as a risk analysis template, You will contribute to research and map drug products with potential supply chain risks. Learning from and collaborating with a team, you will investigate other impurities and contaminants based on high-risk excipient lists from multiple sources. This research will include developing a curated high-risk excipient list based on standard definitions of risk (e.g., ICH Q9), assessment of volume of excipients used (exposure analysis), and analysis of historical product quality defect trends. Integrating these data, you will help assess potential risks due to the complexity and dynamic nature of supply chains.

Learning Objectives: Under the guidance of the mentor, you will acquire a comprehensive understanding of the global supply chain for generics, particularly focusing on injection, otic, and ophthalmic drug products. You will gain experience evaluating the safety and manufacturing considerations of generic drug products approved in multiple jurisdictions and identifying similarities and differences across regions. Additionally, you will be able to develop



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expertise in obtaining and analyzing publicly available formulation, safety, and manufacturing information for generic drug products; and gain understanding of the scientific rationale and regulatory perspectives governing the utilization of foreign comparator products in bioequivalence studies within the US.

Mentor: The mentor for this opportunity is Raphael Brykman (Raphael.Brykman@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the [Guidelines for Non-U.S. Citizens Details page](#) of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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 Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see [FDA Ethics for Nonemployee Scientists](#).

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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 or be currently pursuing a **master's or doctoral degree in one of the relevant fields** (health sciences, pharmaceutical outcomes and policy, pharmaceutical sciences, pharmacology, pharmacy, chemistry, and medical sciences). Degree must have been earned within the past five years or is pursuing and anticipated to be received by 10/30/2026.

Preferred skills:

- Basic awareness of pharmaceutical drug regulations, including drug registration and listings criteria and pharmaceutical product stages (key regulatory starting materials, excipients, API, FDF).
- Knowledge and experience in with complex and large data sets and mapping complex supply chains.
- Quality risk management principles (ICH Q9).

Point of Contact [Ashley](#)

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 10/30/2026 12:00:00 AM.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** ([1](#))
 - **Life Health and Medical Sciences** ([2](#))

Affirmation I am a U.S. citizen, or 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.)
and
I have read the FDA Ethics Requirements.