Opportunity Title: FDA Determination of Qualification Limits for Peptide-related Impurities of Follow-on Products to Inform Guidance
Opportunity Reference Code: FDA-CDER-2026-0192

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

Reference Code FDA-CDER-2026-0192

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.

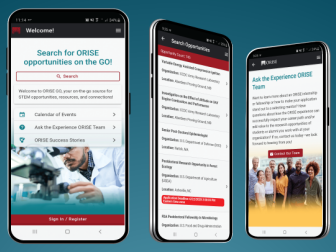
Application Deadline 1/1/2027 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at White Oak, 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: This project will concentrate on establishing Immunogenicity-Based Qualification Thresholds for Peptide and Protein Impurities as well as assessing HLA-Restricted T-Cell and Anti-Drug Antibody Risk. Per regulation, follow-on peptide and protein therapeutics approved under the 505(j) and 505(b)(2) pathways may not require new clinical trials when bioequivalence and qualitative comparability to the reference product are demonstrated. However, differences in product quality attributes (including sequence variants and process/product-related impurities) may alter immunogenicity risk and affect safety, pharmacokinetics, pharmacodynamics, and efficacy. Current FDA guidance (e.g., the 2021 guidance for certain highly purified synthetic drug products referencing rDNA origin drugs) provides analytical qualification limits for impurities but does not establish thresholds based on immunogenicity risk. This creates regulatory uncertainty for industry applicants and reviewers. The proposed project addresses this gap by experimentally defining

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impurity qualification thresholds that incorporate immunogenicity risk and mechanistic understanding of HLA-restricted T-cell activation.

Learning Objectives: Under the guidance of a mentor, you will gain experience in and learn to:

- Identify Impurity-Derived Neoepitopes via Immunopeptidomics
- Define Functional T-Cell Activation Thresholds In Vitro
- Elucidate HLA-Restricted Mechanisms of Drug-Specific T-Cell Responses
- Validate Translational Relevance in Humanized HLA Mouse Models

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

Anticipated Appointment Start Date: 2026/2027. 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.

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.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

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.)