**Opportunity Title:** FDA Fellowship in Nasal and Pulmonary Drug Delivery and In Vitro Permeability Research
**Opportunity Reference Code:** FDA-CDER-2026-0162

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

**Reference Code** FDA-CDER-2026-0162

**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** 11/6/2026 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. These efforts cover more than just medicines.

**Research Project:** You will have the opportunity to participate in a multidisciplinary regulatory science project evaluating biorelevant in vitro methods for characterizing the performance of nasally administered drug products. The funded project will initially focus on naloxone hydrochloride and nalmefene hydrochloride nasal spray products indicated for opioid-overdose reversal. The research will investigate whether regional nasal deposition, epithelial permeation, and drug–mucus interaction measurements can generate evidence relevant to the development of alternative bioequivalence approaches for generic products that are not qualitatively and quantitatively the same as their respective reference products.

Under the guidance of FDA mentors, you will receive training and participate in the design, conduct, optimization, and interpretation of in vitro studies using human-relevant respiratory epithelial models. Experimental activities may include epithelial cell or tissue culture, permeability and transport testing, aerosol- or cloud-based exposure, assessment of epithelial barrier integrity and assay performance, regional deposition testing, mucus-binding studies, quantitative sample analysis, and evaluation of experimental variability.

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The methods and scientific principles involved are relevant across nasal and pulmonary drug delivery. Experience obtained using nasal epithelial models, pulmonary epithelial models, immortalized cell lines, primary cells, air–liquid interface cultures, reconstructed human tissues, microphysiological systems, or other respiratory in vitro models may be applicable to the project.

You will collaborate with scientists with expertise in pharmaceutics, biopharmaceutics, nasal and inhalation drug products, cell-based methods, analytical chemistry, bioequivalence, computational fluid dynamics, and physiologically based pharmacokinetic modeling. You will also have opportunities to analyze and communicate research findings through reports, scientific presentations, conference contributions, and manuscripts.

**Learning Objectives:** Under the guidance of FDA mentors, you will have opportunities to:

- Develop a mechanistic understanding of nasal and pulmonary drug delivery, including the effects of formulation, device performance, regional deposition, mucus interactions, and epithelial barrier properties on drug absorption.
- Gain hands-on experience designing, conducting, troubleshooting, and interpreting in vitro permeability and transport studies using relevant nasal or pulmonary epithelial cell and tissue models.
- Develop experience with respiratory cell culture and model characterization.
- Learn approaches for evaluating assay suitability, barrier integrity, recovery or mass balance, reproducibility, variability, model limitations, and the biological relevance of permeability measurements.
- Participate in biorelevant characterization of naloxone hydrochloride and nalmefene hydrochloride nasal drug products.
- Learn how in vitro deposition and permeability data may be integrated with formulation and device attributes and may inform future computational fluid dynamics or physiologically based pharmacokinetic modeling.
- Strengthen competencies in experimental design, quantitative data analysis, scientific documentation, multidisciplinary collaboration, technical writing, and presentation of regulatory science research.

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

**Anticipated Appointment Start Date: November 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.

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 be currently pursuing or have received a master's or doctoral degree in the one of the relevant fields (pharmaceutical sciences, pharmaceutics, drug delivery, biomedical or bioengineering, chemical engineering, biology, cell or molecular biology, physiology, pharmacology, toxicology, chemistry, or a closely related scientific or engineering discipline). Degree must have been received within the past five years or be currently pursuing.

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Candidates with strong transferable experience in cell-based permeability, respiratory models, pharmaceutical product testing, or drug-delivery research are encouraged to apply.

**Preferred skills:**

- Experience in cell-based permeability, respiratory models, pharmaceutical product testing, or drug-delivery research.
- Nasal, pulmonary, inhalation, respiratory, or other mucosal drug-delivery research.
- In vitro permeability, transport, absorption, or drug-disposition testing.
- Mammalian or respiratory epithelial cell culture, including nasal or lung cell lines, primary cells, air–liquid interface cultures, reconstructed human tissues, organ-on-a-chip systems, or microphysiological systems.
- Comparison or qualification of different epithelial cell lines or tissue models for permeability testing.
- Transwell systems, diffusion cells, aerosol or cloud exposure systems, or related in vitro exposure platforms.
- Nasal spray, inhalation product, aerosol, regional deposition, or drug–device combination-product characterization.
- Measurement of epithelial barrier integrity, cell viability, permeability coefficients, drug recovery, mass balance, or related assay-performance parameters.
- Analytical or bioanalytical techniques such as high-performance liquid chromatography, ultra-performance liquid chromatography, liquid chromatography–mass spectrometry, or other quantitative analytical methods.
- Experimental design, method development or optimization, statistical analysis, and interpretation of complex laboratory data.
- Scientific writing, technical documentation, oral presentation, and collaboration within multidisciplinary research teams.

**Point of Contact** Ashley

**Eligibility Requirements**

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Engineering** (29 👁)
  - **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.)
and
I have read the FDA Ethics Requirements.