Opportunity Title: FDA Data Analytics for CGMP Compliance: Evaluating Regulatory Action Patterns
Opportunity Reference Code: FDA-CDER-2026-0132

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

Reference Code FDA-CDER-2026-0132

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 8/28/2026 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 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. These efforts cover more than just medicines.

Research Project: You will engage in a comprehensive research initiative focused on analyzing current good manufacturing practice (CGMP) drug regulatory actions (warning letters, import alerts, regulatory meetings, consent decrees) and their outcomes to enhance public health protection. You will investigate the landscape of compliance actions against pharmaceutical firms that violate CGMP regulations, with particular emphasis on understanding the relationship between enforcement timeframes and public health outcomes.

You will collaborate with OMQ staff to research and analyze data from FDA's internal compliance management system, with both structured and unstructured datasets. Key activities include investigating patterns in regulatory actions, analyzing temporal relationships between enforcement activities and compliance outcomes, and contributing to the development of evidence-based insights that inform enforcement policy development and

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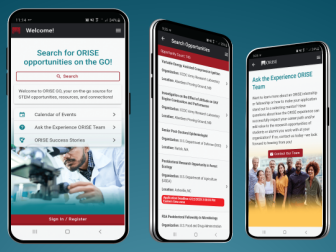

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process improvement initiatives.

This fellowship directly advances FDA's regulatory science mission by contributing to evidence-based improvements in pharmaceutical manufacturing oversight. Your reserach will support OMQ's efforts to optimize enforcement strategies, ultimately enhancing drug safety and quality for American consumers. The educational experience will prepare you to address evolving challenges in pharmaceutical manufacturing and compliance

Learning Objectives: The fellowship will provide you with structured learning opportunities in multiple domains:

- Participate in comprehensive training on CGMP regulations, policies, and enforcement procedures
- Investigate the regulatory framework governing pharmaceutical manufacturing quality
- Research enforcement tools available to OMQ and their appropriate applications
- Analyze complex datasets using Excel, PowerBI, and other analytical platforms
- Participate in data manipulation and validation exercises across multiple database systems
- Contribute to the development of data visualization and reporting methodologies
- Collaborate on research design for compliance outcome studies
- Investigate statistical methods for analyzing regulatory action effectiveness
- Participate in structured approaches to synthesizing findings from diverse data sources

Upon completion of the fellowship, you will have gained:

- Comprehensive understanding of CGMP regulations and their public health significance
- Knowledge of FDA's compliance and enforcement processes within the pharmaceutical manufacturing sector
- Insight into policy development processes and their connection to regulatory science
- Proficiency in manipulating and analyzing large, complex regulatory datasets
- Ability to identify trends and patterns in compliance actions and outcomes
- Skills in developing evidence-based reports and recommendations for process improvement
- Understanding of FDA's organizational structure and agency functions
- Experience in collaborative research within a regulatory environment
- Competency in communicating scientific findings to diverse stakeholders
- This fellowship experience will significantly advance your career preparation in regulatory science and public health:
- The research conducted will contribute to your understanding of real-

world applications of regulatory science principles
- Findings may support thesis research, publications, or conference presentations in pharmaceutical regulation and public health
- Experience will provide foundation for advanced study in regulatory affairs or related fields
- Exposure to FDA's mission will prepare you for careers in regulatory science, pharmaceutical compliance, or public health policy
- Networking opportunities with regulatory professionals will enhance career prospects in government, industry, or academia
- Hands-on experience with regulatory databases and analytical tools will provide valuable technical credentials

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

Anticipated Appointment Start Date: September 14, 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for eight months, 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 and Lawful Permanent Residents (LPR) only.

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 an associate's, bachelor's, master's, or doctoral degree in the one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Associate's Degree, Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12)
  - **Communications and Graphics Design** (2)
  - **Computer, Information, and Data Sciences** (5)
  - **Engineering** (2)
  - **Life Health and Medical Sciences** (51)
  - **Mathematics and Statistics** (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.