



# Office of Clinical Pharmacology

## Fellowship Program for Training in Policy Development and Regulatory Science (OCP Policy and Research Fellowship)

Clinical pharmacology impacts every aspect of drug development, including characterizing the pharmacokinetics and pharmacodynamics of a drug, informing the selection of appropriate clinical doses, deriving dosing for patients with comorbidities and organ impairment, determining the potential for drug interactions, evaluating the impact of genetic factors on drug response variability, and effectively communicating such information in labeling, among other functions.

At the Food and Drug Administration (FDA), the Office of Clinical Pharmacology (OCP) ensures the safety and effectiveness of therapeutics by leveraging clinical pharmacology information such as drug disposition, disease biology, pharmacology, and determinants of response variability and translating this information into clinical recommendations for patients and practitioners. While this expertise is brought to bear at the individual therapeutic product development level, OCP staff also synthesize regulatory experience across therapeutic areas and across the drug product life cycle. Therefore, OCP is positioned to support and advance drug development by training a workforce to collaboratively develop scientific and/or regulatory guidance and policy in the multidisciplinary field of clinical pharmacology. For more information about OCP, please visit [OCP's website](#).

### **Fellowship Goals and Overview**

OCP's Guidance and Policy Team (GPT) hosts an annual one-year ORISE (Oak Ridge Institute for Science and Education) fellowship to train 1 to 2 individuals to conduct OCP and FDA policy evaluations and regulatory science aimed at advancing new drug development and promoting therapeutic individualization. Fellows will scope out and conduct policy and regulatory research project(s) of interest to themselves and the Office under the guidance of mentors. Deliverables for the fellowship may include publications, poster presentations, and use of research results to inform scientific and regulatory policy and processes in OCP. The fellowship runs approximately from September to August every year.

For more information about GPT, please see the following publication - <https://pubmed.ncbi.nlm.nih.gov/32430963/>. For more general information about FDA ORISE fellowships and onboarding through FDA ORISE, please visit <https://orise.orau.gov/fda/>.

### **Fellowship Structure and Curriculum**

The OCP fellowship includes three components: 1) OCP and FDA policy evaluations mentioned above, 2) self-guided didactic training through the FDA scientific and professional courses, and 3) additional projects and activities for fellow-specific professional development. Fellowship mentoring will also be determined by the fellow's style and professional interests. Please see below for information on past fellow's projects.

## **Qualifications**

Prospective fellows should have an advanced degree in a STEM or health-related field (e.g., MS, PhD, PharmD, and/or MD) received within 5 years of the fellowship start month. Due to ORISE security requirements, foreign nationals must have resided in the U.S. for at least three of the past five years. Stipend will be commensurate with experience. Additionally, the prospective fellows should possess excellent analytical, written, and oral communication skills, and have a profound interest in leading projects that advance regulatory science and public health.

## **Application**

The application process has four steps:

1. **Initial Application**: The fellowship will typically be advertised in January to March in the [Zintellect](#) website as an ORISE fellowship. Follow the website instructions to apply for the fellowship.

\* Applications will only be accepted when the application cycle is open.

2. **Policy Memo Writing Exercise**: Those applicants selected as ‘semi-finalists’ will be asked to complete a one-page policy writing exercise. We will provide a writing prompt and high-level review article about a current policy issue in drug development and regulation. All applicants will receive the same prompt and article, and the selected topic will not require extensive knowledge of drug development.
3. **Interview**: Those applicants selected as ‘finalists’ will be invited for an interview (virtual interviews are an option). The purpose of this interview will be to meet the OCP personnel, discuss the applicant’s goals for the fellowship, and potential projects.
4. **Final selection**: Please note that fellows will be onboarded through ORISE - <https://orise.orau.gov/fda/>. The location of this fellowship will be the FDA White Oak Campus in Silver Spring, MD.

## **Past Fellows and Projects**

### **2017-2018: Daphney Jean, PhD ([daphney.jean@fda.hhs.gov](mailto:daphney.jean@fda.hhs.gov))**

- **Topic**: Defining Best Practice Standards for Documentation of Exposure-Response Analysis
- **Fellowship Deliverables**:
  - Poster at 2018 OCP Science Day (internal FDA event)
  - Poster at 2018 Annual Meeting for the American College of Clinical Pharmacology (ACCP) - Poster #103 [Found Here](#)
  - Internal best practices check list
- **Impact on OCP**: Fellowship project results informed internal best practice documents on documenting exposure-response analysis
- **Next Position after Fellowship**: Regulatory Health Project Manager in OCP’s Executive Program/ Project Management Staff

### **2018-2019: Daphne Guinn, PhD ([daphne.guinn@fda.hhs.gov](mailto:daphne.guinn@fda.hhs.gov))**

- Topics:
  - Characterizing Current Labeling Communication of the Clinical Impact of Immunogenicity
  - Elucidating the Impact of Immunogenicity Assessment Post-Approval: A Targeted Analysis of Immunogenicity Post-Marketing Requirements and Commitments
- Fellowship Deliverables:
  - Poster at 2019 OCP Science Day (internal FDA event)
  - Poster at 2019 Annual DIA Meeting - [Found Here](#)
  - Poster presentation at 2020 OCP Science Day (internal FDA event)
  - Two manuscripts
  - <https://pubmed.ncbi.nlm.nih.gov/33258100/>
  - <https://pubmed.ncbi.nlm.nih.gov/32895941/>
- Impact on OCP: Fellowship project results informed FDA documents related to immunogenicity
- Next Position after Fellowship: Regulatory Health Project Manager in OCP's Executive Program/ Project Management Staff

#### **2019-2020: Lingshan Wang, PharmD, MA**

- Topic: Characterizing FDA Advice on Dosing and Its Impact on Adoption of Responses-Guided Titration Approaches During Drug Development
- Deliverables:
  - Poster presentation at the 2020 OCP Science Day (internal FDA event)
  - Poster presentation at the 2020 ACCP annual meeting – Poster # 089 [Found Here](#)
  - Two manuscripts
    - <https://pubmed.ncbi.nlm.nih.gov/33022770/>
    - <https://pubmed.ncbi.nlm.nih.gov/32663324/>
- Impact on OCP: Fellowship project results laid the groundwork for internal best practices related to response-guided titration
- Next Position after Fellowship: Reviewer in OCP

#### **2020-2021: Gelareh Vinueza, PhD**

- Topic: Analyzing Pediatric Dosing for Locally Acting Drugs in Submissions to the FDA Between 2002-2020
- Fellowship Deliverables:
  - Poster at the 2021 annual American College of Clinical Pharmacology (ACCP) meeting
  - 2021 ACCP's Student and Trainee Abstract Award (Poster #109 Abstract [here](#))
  - Manuscript in preparation on the results of the project
- Impact on OCP: Fellowship project results provided a landscape analysis of regulatory practices for dosing of locally acting drugs in pediatric population
- Next Position after Fellowship: Scientific Portfolio Analyst at the NIH's Office of Portfolio Analysis

#### **2020-2021: Sarah Ridge, PhD**

- Topic: A landscape analysis of clinical pharmacology postmarketing studies established between 2009 and 2020

- *Fellowship Deliverables:*
  - Poster at the 2021 annual American College of Clinical Pharmacology (ACCP) meeting (Poster #109 [Found Here](#))
  - Poster at the 2022 annual American Society for Clinical Pharmacology & Therapeutics (ASCPT) meeting
  - 2022 ASCPT Presidential Trainee Abstract Award
  - Two manuscripts in preparation
- *Impact on OCP:* Fellowship project results provided a landscape analysis and impact assessment of clinical pharmacology postmarketing studies which could inform the future of how such studies are established.

**Contact us:**

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