



# Scientific Careers at FDA: Where Science Meets Regulations and Public Health

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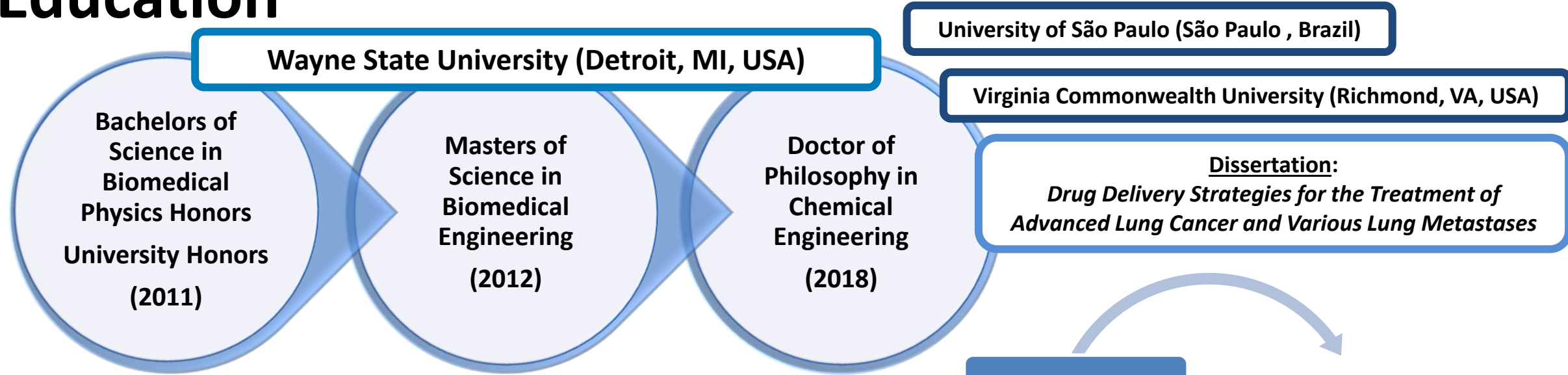
Division of Therapeutic Performance I  
Office of Research and Standards  
Office of Generic Drugs  
CDER | U.S. FDA

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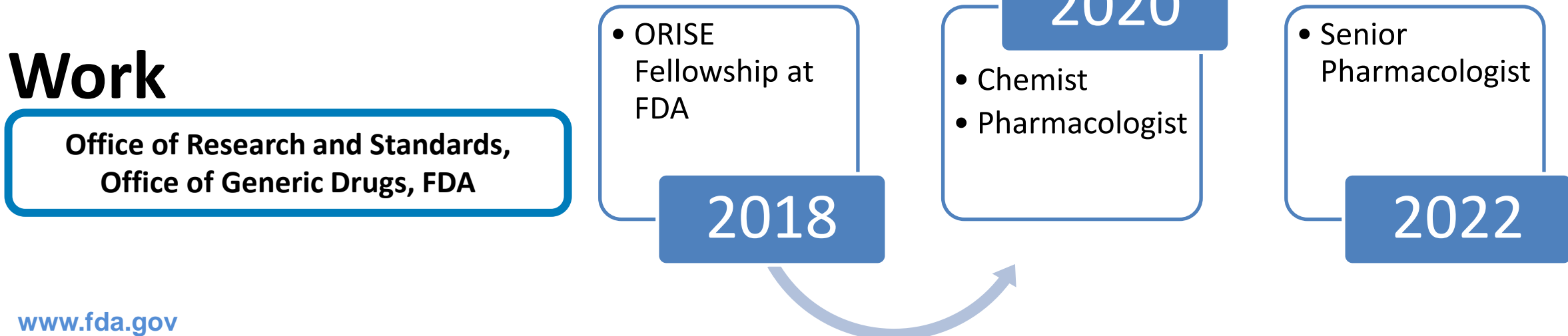


# My Background

## Education



## Work

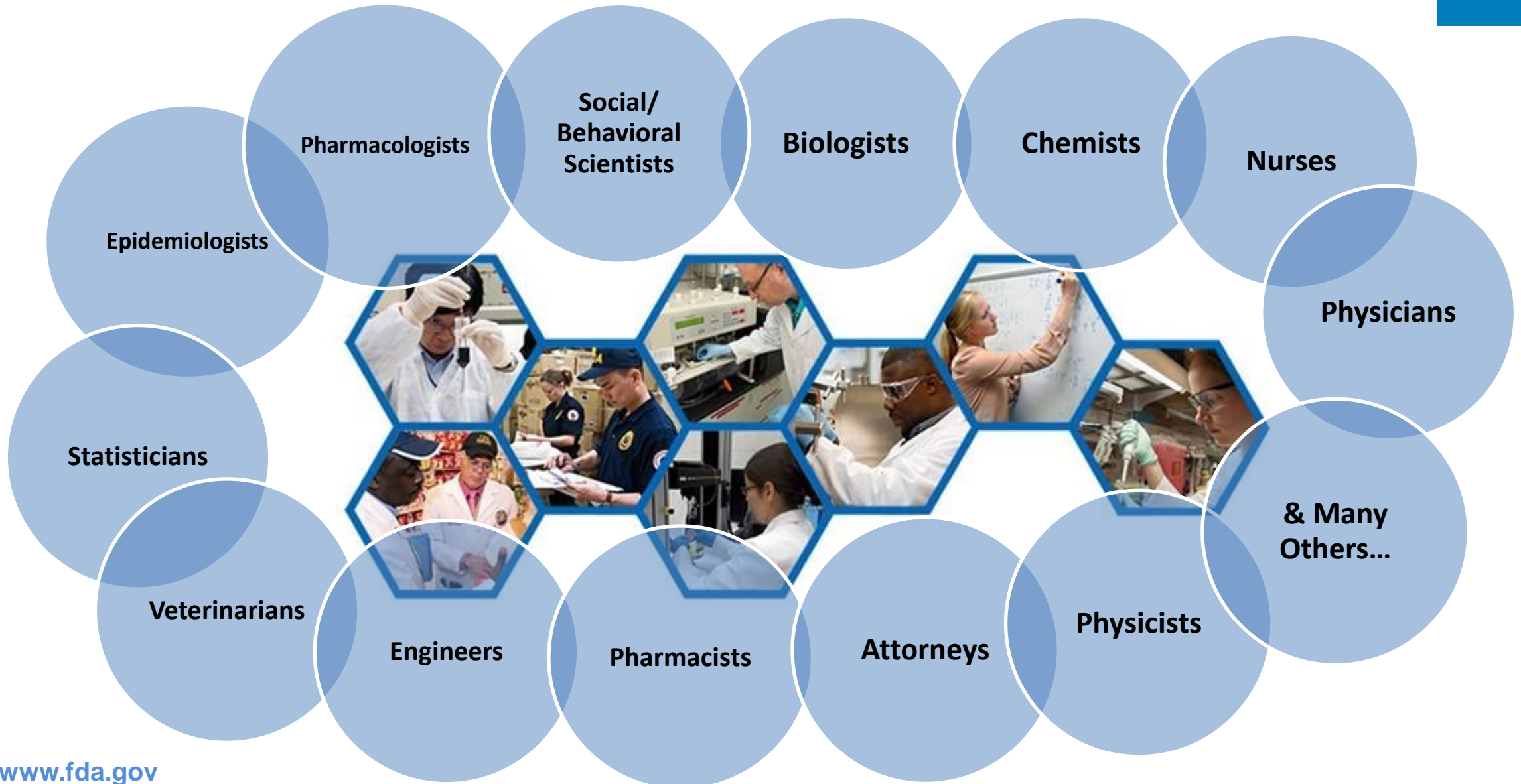


# FDA's Mission



- Protecting the public health by ensuring the *safety, efficacy*, and *security* of human and veterinary **drugs, biological products, and medical devices**.
- Ensuring the *safety* of our nation's **food supply, cosmetics, and products that emit radiation**.
- *Regulating* the manufacturing, marketing, and distribution of **tobacco products** to protect the public health and to *reduce tobacco use by minors*.
- Advancing the public health by *helping to speed innovations* that make medical products *more effective, safer, and more affordable* and by *helping the public get the accurate, science-based information* they need to use medical products and foods to maintain and improve their health.
- FDA also plays a significant role in the *Nation's counterterrorism capability*. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

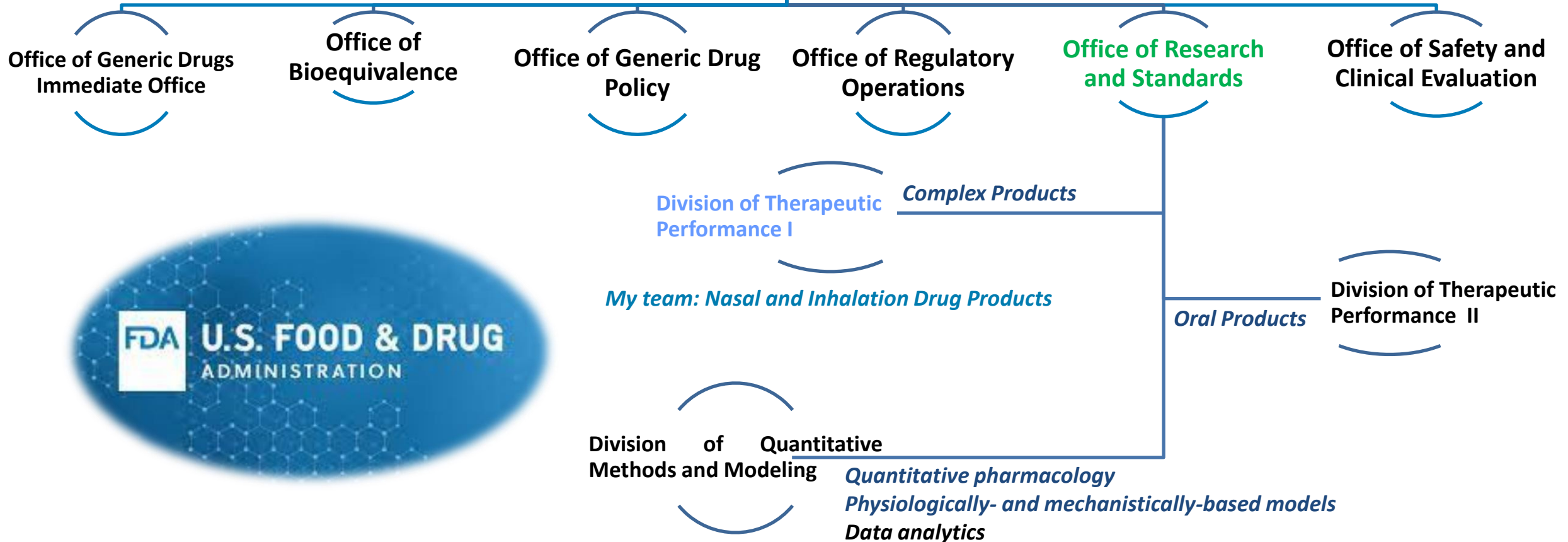
# Who Works at FDA?



# Office of Research and Standards



## Office of Generic Drugs



# Office of Research and Standards

## Generic Drugs – Focus on Complex Drug Products



### Generic Drug Applications: Abbreviated New Drug Applications (ANDA)

#### Regulatory

- **Supports pre-ANDA assessment process (work prior to submission of the applications)**
  - Controlled Correspondences to address industry's scientific inquiries on their generic drug development
  - Pre-ANDA Meetings (Industry Meetings) to provide scientific advice to potential applicants
  - Product-specific guidances to inform industry on suitable study designs for establishing bioequivalence
- **Supports ANDA process via consults**
  - Address scientific questions on current generic drug applications
- **Support scientific questions on policy related concerns (e.g., citizens petitions)**

#### Regulatory Science

- **Conducts regulatory scientific research**
  - Collaborations with academia, industry, and other government agencies
- **Translates regulatory science research into**
  - Scientific posters, presentations, publications
  - General guidances, product-specific guidances, and other documents

*ORS's work is to provide clear pathways and establish standards to ensure therapeutic equivalence of generic versions of complex and non-complex drug products.*

# A Day in the Life in ORS

*Work on a variety of assignments and projects per day*

- **Attend and participate meetings with colleagues**
  - Discuss scientific issues related to assignments, guidances, and various working groups within my team and across the Agency
- **Meet with industry**
- **Write reviews**
  - Controlled correspondences, pre-ANDA meetings, ANDA consults, product-specific guidances, etc.
- **Manage research projects**
  - Meetings with collaborators within and outside FDA
  - Handle contract and grant administrative issues
  - Collaborate on scientific input
- **Attend scientific conferences**
- **Write scientific manuscripts**
- **Attend available trainings and mentorship programs to continue professional development**



# Why Work at FDA?

The logo for the U.S. Food and Drug Administration (FDA), consisting of the letters "FDA" in white on a blue square background.

**Unique Experience: Where Regulations and Science Meet**

**Serve the Health of the U.S. Public**

**Diverse Workforce of Dedicated Professionals**

**Flexible Work Schedules**

**Great Benefits**







# Opportunities at FDA

- **Opportunities:**

## ORISE Fellowships

Currently open Oak Ridge Institute for Science and Education (ORISE) fellowship announcements:

- [FDA Modeling and Simulation Fellowship](#) 
- [FDA In Vitro and In Vivo Bioequivalence Fellowship](#) 
- [FDA Bioequivalence of Complex Generic Products Fellowship](#) 
- [FDA Product Specific Guidance and Research Fellowship](#) 

ORISE Fellowships in ORS:

<https://www.fda.gov/drugs/generic-drugs/generic-drug-research-collaboration-opportunities>.



- **Interested?**

- Reach out to me or others at FDA
  - [Elizabeth.Bielski@fda.hhs.gov](mailto:Elizabeth.Bielski@fda.hhs.gov)
  - Jobs@FDA
  - Zintellect

- **Unsure?**

- Talk to folks at FDA
- Read up on available resources
- Never be afraid to ask questions
- Network

# Resources



- **Scientific Careers at FDA:** <https://www.fda.gov/about-fda/jobs-and-training-fda/scientific-careers-fda#:~:text=FDA%20employs%20scientists%20in%20a,please%20explore%20the%20resources%20below.>
- **White Oak Campus:** <https://www.youtube.com/watch?v=DqimZYtaqHw>.
- **What Does FDA do?:** <https://youtu.be/1D8mOu6SyX4>.
- **U.S. FDA (YouTube):** <https://www.youtube.com/c/USFoodandDrugAdmin>.
- **Generic Drug Research Collaboration Opportunities:** <https://www.fda.gov/drugs/generic-drugs/generic-drug-research-collaboration-opportunities>.
- **Scientific Internships, Fellowships / Trainees and Non-U.S. Citizens:** <https://www.fda.gov/about-fda/jobs-and-training-fda/scientific-internships-fellowships-trainees-and-non-us-citizens>.

