

# Office of Regulatory Affairs (ORA) Office of Biological Products Operations (OBPO) Investigator (Biologics) - Title 21 Band A/B

*Protecting, promoting, and advancing the public health*



You want to  
make a difference.

**FDA**  
wants to  
hire you.

## Investigator (Biologics)

- As an Investigator, you will be responsible for planning and conducting objective surveys, inspections and in-depth investigations of various biologics industry establishments regulated by the Food and Drug Administration; such as blood and blood component manufacturers, tissue processors, re-packers, own label distributors, and biological device and drug firms.
- Investigators in the Biological Products Operations program perform analyses and evaluations on data samples and document information gathered during inspections and investigations in order to ensure that documentation and practices are in compliance with Federal laws, rules and regulations.
- Investigators in the Biological Products Operations program prepares final Establishment Investigation Report (EIR), investigations memorandum, and proposed or final endorsements for inspections, investigations, and filer audits conducted.

## FDA Biological Products Operations Investigators add value by:

- Conducting inspections and scientific evaluation of blood and blood products, unlicensed biological drug products derived from tissue sources including amniotic membrane & umbilical cord tissue, and cellular and tissue-based products (HCTPs 361/351); biological devices; and NDA/ANDA biological drugs.
- Having a direct impact on protecting and promoting the public health and safeguarding biological products.
- Conducting outreach activities with industry associations for training, sharing of current industry trends and agency policy.
- Participating in work groups to continually improve our office, processes, and relationships.
- Interacting with industry and foreign government officials during inspections and international conferences.

## Investigator Qualifications

- A bachelor's degree or higher in quality assurance/management, data science, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food science, law or regulations, or related healthcare or science field. The degree must be from an accredited program or institution.
- Comparable experience with FDA, a state or federal partner agency, or in an FDA-regulated industry or organization providing investigative or compliance services to an FDA-regulated industry, focused on evaluating or ensuring compliance with FDA or related public health laws and regulations.
- Position requires travel up to 50% of the time. Successful candidates should have the ability to travel by car, air, and internationally when needed.

## Investigator Salary (Title 21 Band A/B)

The Title 21 Band A annual salary starts at \$78,592.

The Title 21 Band B annual salary starts at \$94,199.

## Department of Health and Human Services (DHHS)

Become a part of the Department that touches the lives of every American. At the [Department of Health and Human Services \(HHS\)](#) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere!

## US Food and Drug Administration (FDA)

The HHS Food and Drug Administration (FDA) has been recognized as one of the Federal Government's best places to work. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

## FDA Work Life Balance

While making an impact at ORA, additional benefits include: ten paid federal holidays, paid annual leave, sick leave, flexible work schedules, affordable healthcare and insurance, attractive retirement programs, mentoring programs, paid training and professional development tools and resources.

## Office of Regulatory Affairs (ORA)

The Office of Regulatory Affairs, which includes virtually all the field offices of FDA as well as a significant presence in the Washington DC Metropolitan area, serves as the traditional eyes and ears of the agency through its network of investigators and laboratory analysts. ORA works closely with each of the FDA Centers and with other components of the agency to enforce the laws that protect and advance the public health. ORA protects consumers by maximizing compliance of FDA-regulated products and minimizing risk associated with those products. More than 5,000 ORA professionals work in a range of program areas and locations in 227 offices and 13 laboratories throughout the United States every day to maximize compliance of regulated products and to minimize public health risk. ORA regulates more than 135,000 business establishments that annually produce, warehouse, import, and transport \$1 trillion worth of consumer goods.

## Where to Find Jobs & How to Apply

Go to the [ORA Executive and Scientific Positions](#) website to apply for available Investigator positions and submit your application. Your resume will be reviewed by our ORA Invest Recruitment Committee. Check this page often for updates! If you have any questions about when openings may be posted, please contact [ORAINvestigatorHiring@fda.hhs.gov](mailto:ORAINvestigatorHiring@fda.hhs.gov).



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