

# Office of Regulatory Affairs (ORA) Office of Pharmaceutical Quality Operations (OPQO) Investigator (Pharmaceuticals) - Title 21 Band A/B

*Protecting, promoting, and advancing the public health*



## Investigator (Pharmaceuticals)

- As an Investigator, you will be responsible for conducting regulatory inspections and in-depth investigations of various industry establishments, such as manufacturers, re-packers, own label distributors, and importers.
- Investigators in the Pharmaceutical Quality 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 OPQO prepare final Establishment Investigation Report (EIR), investigations memorandum, and proposed or final endorsements for inspections, investigations.
- Investigators independently plan and conduct regulatory inspections and in-depth investigations of various industry establishments.

## FDA Pharmaceutical Quality Operations Investigators add value by:

- Evaluating and making recommendations on the state of compliance of a firm/individual involved in pharmaceutical, or other FDA regulated product manufacturing.
- Having a direct impact on protecting and promoting the public health and safeguarding pharmaceutical 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 to various manufacturing sites across the US and abroad which may require Investigator to be away from the duty station for up to two to three weeks at a time.
- Candidates must have a valid driver's license to drive a government or privately owned motor vehicle.

## 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 12 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 Investigator 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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