

# Office of Regulatory Affairs (ORA) Chemist GS-1320-5/13

Conducting Laboratory Testing of FDA Regulated Drug Products and Ingredients to Ensure Compliance with Good Manufacturing Practices (GMP)



#### Chemist

- Has an immediate impact on the safety of food, drug, and medical device industries and assures the data integrity in support of new drug product applications.
- Performs a variety of scientific testing of FDA regulated products to ensure FDA safety regulations are met.
- May also accompany agency personnel on inspections and serve as a technical advisor.
- Conduct laboratory drug testing for products and ingredients in the US supply chain to ensure regulatory compliance with Good Manufacturing Practices (GMP).

# **ORA Chemists add value by:**

- Analyzing difficult, novel, and complex samples of FDA regulated drug ingredients, compound drugs or finished drug products that require development or modification of methods, or in support of new drug applications.
- Reviewing investigational reports and related compliance documentation tied to GMP established by Agency regulations and Federal laws.
- Interpreting and evaluating analytical results to determine validity and scientific significance; writing reports that state results and conclusions that document the nature of any regulatory violations.

### Qualifications

A degree in physical sciences, life sciences, or engineering that includes 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics

or

- A combination of education and experience -- course work equivalent to a major, including at least 30 semester hours in chemistry, supplemented by mathematics through differential and integral calculus, and at least 6 semester hours of physics, plus appropriate experience or additional education.
- Position requires up to 25% travel away from normal duty station, domestic and international.

# **Chemist Salary (Grade) Levels**

The federal General Schedule (GS) grade levels at which Chemist positions are most commonly filled are GS-9 through 13 at the headquarters level and GS-5 through 12 at the field level.

Note: Higher-grade levels in both headquarters and field offices are available based on peer review of individual accomplishments or supervisory responsibilities). For a list of GS-grade salaries, see the Office of Personnel Management website (<a href="https://www.OPM.gov">www.OPM.gov</a>).

## **Department of Health and Human Services (DHHS)**

Become a part of the Department that touches the lives of every American. At the <u>Department of Health and Human Services (HHS)</u> 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 <a href="www.USAJobs.gov">www.USAJobs.gov</a> and create a profile to upload or build your resume. Type "FDA ORA" in the search bar and your preferred job location (city and state). Apply for available Consumer Safety Officer positions and submit your application. Your resume will be reviewed by our Human Resources Specialists. This review process could take up to 60 days or longer. You can check the Status of your applications at <a href="www.USAJobs.gov">www.USAJobs.gov</a> after signing in to your account and clicking on "My Applications." Current jobs are also listed at <a href="www.fda.gov/orajobs">www.fda.gov/orajobs</a>. Check this page often for updates!

