

ORA Microbiologist/Biologist GS-401/403-7/12

Conducting Laboratory Testing of FDA Regulated Products to Ensure Compliance with Goods Manufacturing Practices



Who We Are

We are FDA's lab analysts who perform a variety of scientific testing on samples of FDA regulated products to ensure FDA regulations are met.

We accompany

agency personnel on inspections and serve as technical advisor; we conduct laboratory testing for products and ingredients in the US supply chain to ensure regulatory compliance with Goods Manufacturing Practices (GMP).



Without the detailed and critical work of FDA laboratories, the FDA could not easily prove violations of GMPs, and hold U.S. companies accountable to regulatory safety standards.

Major Job Duties

Analyze difficult, novel, and complex samples of FDA regulated products that require development or modification of methods.

Reviews investigational reports and related compliance documentation tied to Goods Manufacturing Practices established by Agency regulations and Federal laws.

Interprets and evaluates analytical results to determine validity and scientific significance; writes reports stating results and conclusions documenting the nature of any regulatory violations.

Qualifications

Series 403—Biology: Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. OR

Combination of education and experience: Courses equivalent to a major, as shown above, plus appropriate experience or additional education.

Series 401—Microbiology: Degree: microbiology; or biology, chemistry, or basic medical science that included at least 20 semester hours in microbiology and other subjects related to the study of microorganisms, and 20 semester hours in the physical and mathematical sciences combining course work in organic chemistry or biochemistry, physics, and college algebra, or their equivalent. OR

Combination of education and experience: courses equivalent to a major in microbiology, biology, chemistry, or basic medical science that included courses as shown in A above, plus appropriate experience or additional education.

Requires up to 25% travel away from normal duty station, domestic and international.

Where to Find Jobs & How to Apply

Use www.USAJobs.gov to find ORA jobs.

- We recommend you build a resume in USAJobs.gov when searching for a government job.
- Search for: Microbiologist or Biologist Series, GS-0401 and GS-0403

About the Office of Regulatory Affairs (ORA)

The Office of Regulatory Affairs (ORA) is the lead office for all field activities at the FDA. Regulating more than 135,000 business establishments that annually produce, warehouse, import, and transport \$1 trillion worth of consumer goods, ORA protects consumers by maximizing compliance of FDA- regulated products and minimizing risk associated with those products. More than 4,400 ORA personnel in more than 200 locations work every day to maximize compliance of regulated products and to minimize public health risk.

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