

Position Description

Description #: 600273 (Step 4 of 5 from Ladder 600270 - 600274)
 FDA Title: Chemist
 OPM Title: Chemist
 Pay Plan-Series-Grade: GS - 1320 - 11
 Activity Location: OFC OF REGULATORY AFFAIRS
 Duty Location: Various Locations
 Organization Structure: HHS - Food and Drug Administration
 OFC OF REGULATORY AFFAIRS
 OFC OF REGULATORY SCIENCE

Certifications:

I certify that this is an accurate statement of major duties and responsibilities of this position and its organizational relationships, and that the position is necessary to carry out Government functions for which I am responsible. This certification is made with the knowledge that this information is to be used for statutory purpose relating to appointment and payment of public funds, and that false or misleading statements may constitute violations of such statutes or their implementing regulations.

Duties Certified: Mark R. Madson

Date: 12/13/2017

I certify that this position has been classified/graded as required by Title 5, U.S. Code in conformance with standards published by the U.S. Office of Personnel Management or, if no published standards apply directly, consistently with the most applicable published standards.

Classified By: Jeremy W. Kincaid

Date: 12/13/2017

Introductory Statement:

The position is located in the United States (U.S). Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Regulatory Science (ORS). ORA's mission is to protect consumers and enhance public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products. ORA is responsible for inspecting regulated products and manufacturers, conducting sample analyses of regulated products, and reviewing imported products offered for entry into the U.S. The primary purpose of this position is to perform, in a career ladder capacity, assigned chemical analyses on a wide range of samples including those that are difficult, complex, or unusual scientific analyses in support of higher level personnel. S/he, as a part of a planned career development, receives formal and on-the job training, working with and assisting senior Chemists in the performance of a variety of analyses and experiments necessary for carrying out the mission and functional responsibilities of the FDA. The incumbent is eligible for noncompetitive promotion dependent upon meeting applicable qualification requirements and satisfactory demonstration of the ability to perform the duties at the GS-12 level. The primary purpose of this position is to serve as a Chemist in an FDA/ORA field laboratory and is assigned analyses requiring a high degree of expertise in: (1) the typical full range of commodities regulated by FDA; (2) a broad commodity area, i.e., foods, drugs, etc., or (3) a combination of both commodity and instrumentation area which may include the use of computers interfaced with analytical instruments.

(50%) - Performs the full range of analytical chemistry on a variety of samples, including the difficult, complex or unusual samples submitted by agency personnel in connection with regulatory monitoring and enforcement activities. Before analyzing a sample, reviews the background material submitted with the sample, agency reports on similar samples or situations, and pertinent regulations. Determines the approach, methods, and procedures to use to obtain the information requested, taking into consideration the requirements

Major Duties:	<p>established by Agency regulations and Federal law.</p> <p>(25%) - Modifies' the methods and procedures as needed to satisfy special requirements and to solve problems. Includes performing the analyses on known samples to validate the modification. Writes a report that identifies the sample, shows the methods and procedures used, any modifications with validation data, the results and their interpretation, and whether the sample appears to be in violation of any agency regulation.</p> <p>(25%) - Provides training for less experienced scientists on the precedents, analytical methods and instrumentation related to the scientific discipline of the position. As assigned, accompanies Agency personnel on field inspections/investigations and acts as a technical advisor.</p>
Other Duties:	<p>Performs other duties as assigned.</p>
Position Requirements:	<p>This position requires the incumbent have the following current License and/or Certification: Must maintain a valid state issued driver's license.</p> <p>This position requires up to 25% travel.</p>

Factor Evaluation System (FES)

Grade: 11 Total Points: 2470 Points Range: 2355 - 2750

1. Knowledge Level: 7 Points: 1250

Professional knowledge of chemical principles, theories, practices, and established methodologies sufficient to perform the full range of duties involved in analyzing a wide variety of drug, food, and cosmetic samples. Knowledge of established FDA laboratory procedures, the FDandC Act and related regulations, other laws, and court precedents which apply to laboratory operations, inspections, investigations, and various regulatory actions. Knowledge of practices and related problems associated with the raw materials, products or manufacturing for the industries or commodities in assigned responsibility. Skill in oral and written communication to prepare and present analyses; provide guidance; solicit information; draft position papers; defend proposals; and prepare materials to support work. Skill in gathering, assembling, consolidating, and analyzing data and drawing conclusions to identify trends and developments which will enhance the various programs' processes, functions, and systems and to determine the nature of vaguely defined problems

Position Unique Knowledge 1

Knowledge of established FDA laboratory procedures, the FDandC Act and related regulations, other laws, and court precedents which apply to laboratory operations, inspections, investigations, and various regulatory actions. Knowledge of practices and related problems associated with the raw materials, products or manufacturing for the industries or commodities in assigned responsibility.

2. Supervisory Controls Level: 4 Points: 450

The supervisor assigns the work by setting the overall objectives and the resources available. The incumbent is then responsible for planning, organizing and performing the work, determining the best approach and methods to use making modifications as needed, and interpreting the results. The completed work is reviewed from an overall standpoint for feasibility and effectiveness in meeting the assignment's requirements.

3. Guidelines Level: 3 Points: 275

The guidelines include precedents, scientific literature, laboratory procedures and methodology manuals, instrument handbooks, and agency policies. These guides are not always specifically applicable to the assignment at hand. Judgment must be used to interpret and adapt the guidelines to specific cases. The incumbent will analyze results and recommend changes.

4. Complexity Level: 4 Points: 225

The chemistry analytical assignments include the difficult, complex, or unusual samples and analytical requests received in the laboratory. Typically, the specific data needed and the approach to be taken to obtain these data are uncertain. To make these decisions and to interpret the final results, the work requires evaluation and interpretation of data from a wide range of sources such as the background material submitted with the analytical request, reports on similar samples or problems, technical references, and trade literature, in addition to consideration of pertinent regulations. Adaptation or modification of the established methods and procedures is often required to plan and carry out the work.

5. Scope & Effect Level: 3 Points: 150

The work primarily involves fulfilling a range of conventional chemical analytical requests by applying established precedents and methods to the scientific analyses of a variety of foods, drugs, or cosmetics and making method modifications if necessary. The work efforts affect the scientific adequacy and accuracy of regulatory field investigations and studies.

6. Personal Contacts Level: 3 Points: 60

The personal contacts are with scientific personnel in the Agency, other governmental and state organizations, and private industry.

7. Purpose of Contacts Level: 2 Points: 50

The personal contacts are to discuss with other scientists' methodological problems, possible solutions, and method modification projects in addition to reporting the status of the work and the results.

8. Physical Demands Level: 1 Points: 5

This FL meets 8-2 for 20 pts: Work may involve exposure to chemical and biological hazards that may require special safety precautions. May need to use protective clothing and equipment. To perform the work of the position, the employee must possess a valid driver's license to drive a Government or privately owned motor vehicle to inspections and investigations. The position may require the need to work long and unscheduled hours; exposure to various extremes of weather and noise; the need to lift heavy objects up to 50 pounds, walk, bend, stand, stoop, kneel, and climb; the need to meet the vision, hearing and olfactory requirements necessary to perform the work of the position; and the need to travel, as required by management needs, may require the incumbent to be away from the regular duty station for multiple weeks at a time.

9. Work Environment Level: 1 Points: 5

FL 9-2 is met for 20 pts. The work involves regular and recurring exposure to irritant chemical and biological hazards. Special safety precautions are required, and the regulatory scientist may be required to use protective clothing and gear such as a laboratory coat, safety glasses, latex gloves, mask, etc. When serving as an Investigator, inspection and sample collection duties are performed either inside buildings and other structures, outdoors or both depending on the type and location of the facility. Consequently, employees are exposed to a variety of environmental conditions including extremes of heat, cold or humidity; excessive noise; excessive dust; uneven surfaces and slippery floors; and extremely adverse conditions during natural and other disasters such as floods, fires, hurricanes, etc. During these periods, employees must eat and sleep in primitive conditions with little or no privacy. As Investigators, must travel into and work in areas that have been the subject of violence and that are otherwise considered unsafe.