

Job Title: Quality Assurance Specialist**Department:** Department Of Health And Human Services**Agency:** Food and Drug Administration**Job Announcement Number:** PH-JP-10-329764

Salary Range: 105,211.00 - 136,771.00 USD /year

Series & Grade: GS-1910-14

Promotion Potential: 14

Open Period: Monday, March 29, 2010 to Friday, April 23, 2010

Position Information: Full Time Career/Career Conditional

Duty Locations: 01 vacancies - Silver Spring, MD

Who May Be Considered: United States Citizens

Job Summary:

Become a part of the Department that touches the lives of every American! At the Department of Health and Human Services you can give back to your community, state, and country by making a difference in the lives of Americans everywhere. Join HHS and help to make our world healthier, safer and better for all Americans.

- Do you want to make a difference in helping support efforts to align FDA priority initiatives for the 21st Century?
- Are you interested in interpreting and determining the applicability of quality tools to specific improvements and deficiencies?
- Are you interested in creating new quality tools?

Area of Consideration: All U.S. Citizens and Nationals.

One or more positions may be filled using this vacancy announcement.

Key Requirements:

- You must be a U.S. Citizen or National.
- Resume and supporting documents (See the How To Apply section.)
- Position may require some travel.

Major Duties:

The Quality Assurance Specialist position is located in the Office of Pharmaceutical Science. As the senior Quality Assurance Specialist is responsible for coordinating the development and overseeing the implementation of the Quality Management Plan (QMP) or other established guidelines and supports internal efforts to align FDA with priority initiatives such as Pharmaceutical Current Good Manufacturing Products (cGMP) for the 21st Century. Specifically, the Quality Assurance Specialist:

- Participates in developing, implementing and maintaining the CMC Quality Management Systems and the QMP;
- Leads the line office on program quality related issues and efforts in alignment with all FDA/CDER

efforts;

- Represents the line office as a member of the CMC Quality System Board (QSB) and informs the line Office Director on CMC quality system updates, including any deficiencies or improvements;
- Develops tentative/final operating criteria and procedures, staff and operational quality standards and protocols, and any other communications pertaining to the CMC Quality Management Systems; and
- Coordinates the resolution of line office issues related to the QMS components, including planning, implementation, and evaluation of process improvement tools utilized.

Qualifications:

In order to qualify for the Quality Assurance Specialist, GS-14 you must possess the following:

Possess at least one year of specialized experience equivalent to the GS-13 level in the Federal service, overseeing the activities of Chemistry, Manufacturing, and Controls (CMC) review process and drug testing and scientific evaluation of drug products in support of FDA; complete assessment of product and process design, evaluation of product quality in light of established standards and setting; maintain new quality standards; and keep line Office Director informed of any deficiencies or improvements.

ARE YOU USING YOUR EDUCATION TO QUALIFY? You MUST provide transcripts or other documentation to support your educational claims. Unless otherwise stated: (1) unofficial transcripts are acceptable, or (2) you may submit a list with all of your courses, grades, semester, year, and credit for the course. All materials must be submitted by the closing date of the announcement.

Foreign Education: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For further information, visit:

<http://www.ed.gov/about/offices/list/ous/international/usnei/us/edlite-visitus-forrecog.html>

PART-TIME OR UNPAID EXPERIENCE: Credit will be given for appropriate unpaid work on the same basis for paid experience. Part-time experience will be credited on the basis of time actually spent in appropriate activities. To receive credit for such experience, you must indicate clearly the nature of the duties and responsibilities in each position held and the number of hours per week spent in such employment.

Only experience obtained by the closing date of this announcement will be considered.

Status candidates must meet time in grade requirements (52 weeks at the next lower grade level.)

A favorable background/security investigation under Homeland Security Presidential Directive (HSPD) -12 and other applicable laws and regulations is a condition of employment for this position. A credit check may be required as part of the investigation. An unfavorable adjudication of a background/security investigation may result in your removal from the federal service.

How You Will Be Evaluated:

Once the application process is complete, a review of resume and supporting documentation will be made and compared against your responses to the assessment questionnaire to determine if you are qualified for this job. If, after reviewing your resume and or supporting documentation, a determination is made that you have inflated your qualifications and or experience, you may lose consideration for this position. Please follow all instructions carefully. Errors or omissions may affect your eligibility. Qualified candidates will be assigned to a quality category. The category assignment is a measure of the degree in which your background matches the competencies required for this position. Your qualifications will be evaluated on the following competencies (knowledge, skills, abilities and other characteristics):

- Knowledge of quality assurance principles and practices
- Skill in analyzing scientific issues and improvements in pharmaceutical science
- Ability to communicate technical information orally and in writing

Benefits:

The Federal government offers a number of exceptional benefits to its employees. This link provides an overview of the benefits currently offered to Federal employees. <http://www.usajobs.gov/EI/benefits.asp>

Other Information:

If you are a veteran with preference eligibility and you are claiming 5-points veterans' preference, you must submit a copy of your DD-214 or other proof of eligibility. **If you are claiming 10-point veterans' preference**, you must also submit an SF-15, "Application for 10-Point Veterans' Preference" **plus the proof required by that form**. For more information on veterans' preference see <http://www.usajobs.gov/veteranscenter>

Males born after 12-31-59 must be registered or exempt from Selective Service (see www.sss.gov).

Interagency Career Transition Assistance Program (ICTAP): For information on how to apply as an ICTAP eligible see http://www.opm.gov/rif/employee_guides/career_transition.asp#ictap. To be well-qualified and exercise selection priority for this vacancy, displaced Federal employees must be rated at 85 or above on the rating criteria for this position.

How To Apply:

To apply for this position, you must provide a complete Application Package which includes:

1. Your **Résumé**
2. A complete **Assessment Questionnaire**
3. Other **supporting documents:**
 - Veterans Preference Documentation, if applicable
 - College transcript(s), if qualifying based on education
 - SF-50, Notification of Personnel Action (if applying as a status candidate with current or former Federal service)

The complete Application Package must be submitted by 11:59 PM (EST) on Friday, April 23, 2010.

To begin the process, click the Apply Online button to create an account or log in to your existing USAJOBS account. Follow the prompts to complete the assessment questionnaire. Please ensure you click the **Submit My Answers** button at the end of the process.

Note: To return to a previously Saved or Incomplete application you may use the following link:
<https://applicationmanager.gov/>.

To fax supporting documents you are unable to upload, complete this cover page
<http://staffing.opm.gov/pdf/usascover.pdf> using the following Vacancy ID: PH329764. Fax your documents to **1-478-757-3144**.

If you cannot apply online:

1. Click the following link to view and print the assessment questionnaire [View Occupational Questionnaire](#), and
2. Print this 1203FX form to provide your response to the assessment questionnaire <http://www.opm.gov/forms/pdfimage/opm1203fx.pdf> and
3. Fax the completed 1203FX form along with any supporting documents to **1-478-757-3144**. Your 1203FX will serve as a cover page for your fax transmission.

Required Documents:

The following documents are required and must be received by the closing date of this announcement:

1. Your **Résumé**
2. A complete **Assessment Questionnaire**
3. Other **supporting documents:**
 - Veterans Preference Documentation, if applicable
 - College transcript(s), if qualifying based on education
 - SF-50, Notification of Personnel Action (if applying as a status candidate with current or former Federal service)

Contact Information:

Philadelphia Services Branch
Phone: (215)861-3074
Email: philadelphia@opm.gov

Agency Information:
Philadelphia Services Branch
US Office of Personnel Management
600 Arch Street
Philadelphia, PA 19106
USA

What To Expect Next:

Once the online questionnaire is received you will receive an acknowledgement email that your submission was successful. Based upon your score, you may be referred to the hiring official. If your name is referred to the hiring official, you may be contacted directly by that office for a possible interview. You will receive notice via email or by mail, if no email address was provided by you during the application process, once this process is completed (generally 4-6 weeks).

EEO Policy Statement: <http://www.usajobs.gov/eeo>

Reasonable Accommodation Policy Statement: <http://www.usajobs.gov/raps>

Veterans Information: <http://www.usajobs.gov/vi>

Legal and Regulatory Guidance: <http://www.usajobs.gov/lrg>

Control Number: 1849988