REIMBURSABLE DETAIL
Center for Tobacco Products
Office of Science

The Center for Tobacco Products (CTP), Office of Science (OS) is offering Detail opportunities for a **Regulatory Health Project Manager, GS-601-14**. Applicants at the GS-13 and GS-14 levels are encouraged to apply. The Detail is available immediately for a period of 120 days. Temporary promotions will be considered. Multiple selections may be made from this announcement.

Bargaining Unit Status: Bargaining Unit Position

Office Location: FDA
Center for Tobacco Products
11785 Beltsville Drive
Beltsville, MD 20705
100% Telework until further notice.

Opening Date: **November 9, 2020**
Closing Date: **November 16, 2020**

Area of Consideration: **CTP-Wide**

The CTP Office of Science, Division of Regulatory Science and Management offers a fast-paced, dynamic environment and an opportunity to work with dedicated, energetic people who really want to make a difference and improve public health. The position is ideal for someone who wants to have a critical role in the organization and would enjoy the challenge of handling a variety of assignments related to the regulation of tobacco products.

Duties include:
The incumbent will be a Regulatory Health Project Manager in the Office of Science, Division of Regulatory Project Management, Immediate Office. The incumbent serves as an expert in scientific regulatory project management and tobacco application reviews and deeming, by consistently and appropriately applying up-to-date regulatory knowledge and expertise, institutional guidance and standard operating procedures. The incumbent is responsible for the management of premarket review of tobacco product applications and other regulatory submissions, process development, research projects, as well as other workgroups along with all associated processes for each, including the planning, focusing, and coordinating of the teams' review activities within the Division.

MAJOR DUTIES AND RESPONSIBILITIES

- Serving as a leader or co-leader of scientific projects and/or tobacco application review teams. He/she is responsible for the management activities of the team including participating in the development of scientific strategic planning to enhance the products or services, scheduling meetings, facilitating meetings, and preparing issue-based

agendas and official records of meetings. Each project team is composed of both scientific and regulatory personnel within and outside the office and may include subject matter experts as necessary from other centers and agency organizations. Project team members are accountable both to the team and to their line management.

- Serving as a regulatory expert on review teams and other project teams. The incumbent will participate in determining the appropriate products or services needed to complete the projects. Gives presentations or briefings on the status and all aspects of the projects.
- Completes regulatory reviews that demonstrate a comprehensive and expert knowledge of the most current laws, regulations, guidance, regulatory precedents, and procedures for the assigned technical area.
- Responds to questions and completes written documents that demonstrate technical knowledge and competency in areas of the basic principles and limitations of biological or physical science, manufacturing, public health policies, and regulation of tobacco products.
- Provides advice and consultation on programs and projects that demonstrate technical competency for addressing complex or difficult regulatory science issues and result in a meaningful, specific, and tactical plan to achieve goals
- Working collaboratively with all members of the team (scientific, regulatory and management) to develop project plans, including setting time frames; milestones, and an agreed upon endpoint. Assists in developing the phases, milestones and final project review of the projects. Fostering cooperation, communication and facilitating an open and honest exchange of ideas across disciplines; raising different perspectives when appropriate.
- Monitoring and reporting actual status of all activities within the assigned projects through interaction with project participants and, if required, supervisors and directors. Serving as the primary point of contact for the up-to-date status of project progress and representing the team activities to management. Initiating correspondence regarding action, policy issues or requests for additional information. Identifying project activities or situations that may adversely impact project plan and advising supervisors, team members and management of potential in1pact and, with the team, recommending solutions to problem areas.
- Managing the tobacco product review process from initial submission to the time of regulatory action. Providing advice and counsel to all parties engaged or interested in the FDA tobacco product review process.
- Serving as the contact point for all communications concerning tobacco product applications and other submissions, and ensuring compliance with all legal, regulatory and policy requirements. The employee draws upon his/her knowledge of the Food, Drug, and Cosmetic Act as amended by the Tobacco Control Act, regulations and policies, and related matters to anticipate and identify subtle or obscure problems and to ensure that the review team is aware of these problems and addresses them.
- Manages meetings according to established practices and prepares official meeting records within established timelines. Plans and manages internal meetings (e.g., new submission or other project kick-off, mid-cycle review, wrap-up, pre-industry) to efficiently address objectives for assigned projects, including pre-meeting activities, preparation of issue-based agendas, meeting records, and action items.

- Tracking each application being managed while it is being reviewed by secondary and tertiary reviewers.

Desired Knowledge and Skills:

- Demonstrates advanced knowledge of the Food, Drug, and Cosmetic Act as amended by the Tobacco Smoking Prevention and Tobacco Control Act and related regulations, policies and procedures.
- Demonstrates advanced knowledge and experience in regulatory science and in the analysis and planning of tobacco science projects.
- Expert knowledge of FDA regulations, statutory authorities, policies, and processes.
- Technical knowledge and competency in the areas of basic principles and limitations of biological or physical science, manufacturing, public health policies, and regulations of tobacco products. Skill in applying this knowledge in independently carrying out research or review projects.
- Expert knowledge, skills, tools, and techniques of scientific and regulatory project management to meet project requirements.
- Demonstrated experience effectively planning and managing projects and resources to accomplish a variety of concurrent activities.
- Ability to facilitate meetings.
- Excellent organizational skills.
- Effective verbal and written communication skills.
- Excellent interpersonal and team skills

Application Procedure:

The detail opportunity is open to all qualified candidates at the GS-13 or GS-14 grade level or Commissioned Corps Officers. You must be a CTP employee. A temporary promotion may be available.

Interested applicants should submit a copy of their resume, most recent copy of SF-50, and statement of interest via email to:

Gretchen Winand
Office of Management/Human Capital Team
Gretchen.Winand@fda.hhs.gov

Please indicate in the Subject line of the email: **Detail Application– RHPM, GS-601-14**.

If you are not currently in the GS-601 series, please submit a copy of your unofficial transcript(s).

Detail is reimbursable.
Travel expenses will not be paid.

Candidates must express interest by November 16, 2020.

***This is not an official vacancy announcement under the Merit Promotion System.**