REIMBURSABLE DETAIL
Center for Tobacco Products
Office of Science

The Center for Tobacco Products, Office of Science is offering a Detail opportunity for a **Supervisory Regulatory Health Project Manager, GS-601-15** serving as a Branch Chief in the Division of Regulatory Project Management, Branch IV. Applicants at the GS-14 and GS-15 levels are encouraged to apply. The Detail will be for a period of 120 days. The Detail also may offer multiple rotational opportunities for more than one selection.

Bargaining Unit Status:	Non-Bargaining Unit Position
Office Location:	FDA Center for Tobacco Products 11785 Beltsville Drive Beltsville, MD 20705 Work will be done remotely.
Opening Date:	**November 30, 2020**
Closing Date:	**December 4, 2020**
Area of Consideration:	**FDA-Wide**

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

Duties include:

The incumbent serves as a Supervisory Regulatory Health Project Manager in the Office of Science, working under the general supervision of the Director for the Division of Regulatory Project Management who provides broad administrative and strategic direction, and outlines general and mission concepts. As Supervisory Regulatory Health Project Manager (Branch Chief), the incumbent supervises a staff of ten or more employees who serve as experts in scientific regulatory project management and tobacco application reviews by consistently and appropriately applying up-to-date regulatory knowledge and expertise, institutional guidance and standard operating procedures.

MAJOR DUTIES AND RESPONSIBILITIES

- The incumbent supervises staff responsible for managing scientific projects and/or tobacco application reviews. S/he is responsible for supervising and managing activities

that include strategic planning to enhance the products or services, scheduling meetings, facilitating meetings, and preparing issue-based agendas and official records of meetings. Establishes project teams composed of both scientific and regulatory personnel within and outside the office that may include subject-matter experts as necessary from other centers and agency organizations. Project managers who are responsible for scientific projects and /or tobacco application reviews are accountable both to the technical program lead and to their line management.

- The incumbent plans, organizes, and directs scientific regulatory project management and tobacco application reviews in accordance with Center-wide strategic direction. Implements Center-wide strategies for achieving annual and long-range plans, goal and objectives in assigned areas of specialization. Analyzes review status with respect to variance from project plans and determines impact on established project goals. Identifies and coordinates the resolution of conflicting resource needs, availability, and scheduling.

- Provides authoritative advice and counsel to all parties engaged or interested in the FDA tobacco product review process. Opinions are often precedent-setting and decisions may have major public health and/or economic consequences. Compliance with all legal, regulatory and policy requirements. The incumbent draws upon a comprehensive 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 project teams are aware of these problems and address them.

- Directs a highly-trained professional staff that performs the following duties: Serves as regulatory experts on review teams and other project teams. Acts as the primary contacts for regulated industry, fostering effective communication. Determines the appropriate products or services needed to complete the projects. Gives presentations or briefings on the status and all the aspects of the projects. Assures timely resolution of scientific and regulatory conflicts or problems to avoid delays in achieving goals. Implements and maintains quality control of the scientific projects. Collaboratively leads, manages and coordinates the work of project team members and determines progress and solves problems. Monitors and reports status of activities within the assigned projects through interaction with project participants and, if required, supervisors and managers. Initiates correspondence regarding action, policy issues or requests for additional information. Identifies project activities or situations that may adversely impact project plan and advises supervisors, team members and management of potential impact and recommends solutions to problem areas.

- The Supervisory Regulatory Health Project Manager works collaboratively with all Office of Science management and project team members (scientific, regulatory and management) to develop project plans, including setting time frames, milestones, and an agreed-upon endpoint. Designs and develops the phases, milestones and final project review of the projects. Fosters cooperation, communication and facilitates with an open

and honest exchange of ideas across disciplines, raising different perspectives when appropriate.

- The Supervisory Regulatory Health Project Manager may also be assigned other responsibilities or special projects that are commensurate with his/her background and capabilities. Such assignments may include presentations at internal meetings, conferences and professional meetings with public health organizations, regulated industry, and the research community.

- Advises and assists the Office Director, Division Director and other key officials on scientific regulatory project management and tobacco application review issues that impact policy, direction and long-range goals.

- Develops policies and programs involving the most complex and highest priority project management and tobacco application review issues affecting the regulations of the Center for Tobacco Products. Drafts or critically reviews documents embodying policy and program proposals and decisions on projects managed.

- Contributes to the preparation of scientific papers, congressional correspondence and testimony, Federal Register documents, technical reports and private sector information programs.

Supervisory Duties (25%):

Plans and schedules work to be accomplished by subordinates, sets and adjusts long- and short-term priorities, and prepares schedules for completion of work, when necessary. Assigns work to subordinates based on priorities, considering difficulty and requirements of assignments as well as the capabilities of employees. Develops performance standards and evaluates work performance of subordinate staff. Provides advice, counsel, or instruction to employees on both work and administrative matters. Interviews candidates for positions on the staff. Makes selections for appointment, promotion, or reassignment of employees. Addresses and resolves employee-related matters such as grievances and other serious unresolved matters to a higher-level supervisor for resolution as needed. Effects minor disciplinary measures, such as warnings and reprimands. Identifies developmental and training needs of employees and provides for or arranges for needed development and training. Identifies ways to improve production or increase the quality of the work directed.

Qualifications Required;

- Expert knowledge of scientific regulatory project management.
- Comprehensive knowledge of the Tobacco Control Act.
- Ability to provide authoritative advice and counsel on the FDA tobacco review process.
- Ability to develop project plans.
- Ability to make presentations and represent the Branch and Division.
- Ability to communicate and foster cooperation among teams and across scientific disciplines.

Application Procedure:

The detail opportunity is open to all qualified candidates at the GS-14 and GS-15 grade levels or Commissioned Corps officers. A temporary promotion will be considered.

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/Division of Human Capital
Gretchen.Winand@fda.hhs.gov

If you are not currently in the GS-600/601 series, please provide a previous SF-50 showing the GS-600 series appointment or an unofficial copy of your transcripts.

Please indicate in the Subject line of your application email:
Detail – Supervisory RHPM, GS-601-15 – December 2020

Detail is reimbursable.

Travel expenses will not be paid.

Candidates must express interest by December 4, 2020.

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