REIMBURSABLE DETAIL Center for Tobacco Products Office of Science

The Center for Tobacco Products, Office of Science (OS), Immediate Office (IO) is offering a detail opportunity to Unclassified Duties (Substantial Equivalence Program Coordinator) GS-601-14. Applicants at the GS-14 level are encouraged to apply. The Detail is available immediately for a period of 120 days. Commissioned Corps Officers are encouraged to apply. A temporary promotion may not be considered.

Bargaining Unit Status: Bargaining Unit Position

Duty Location: Anywhere in the U.S. (REMOTE)

Office Location: FDA

Center for Tobacco Products

11785 Beltsville Drive Beltsville, MD 20705

Opening Date: May 04, 2023 Closing Date: May 17, 2023

Area of Consideration: HHS-Wide

The CTP, Office of Science (OS) 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:

As a Substantial Equivalence (SE) Program Coordinator, the incumbent serves as the central management and coordination of the SE review program. Works with the Office of Science Executive Leadership Team (ELT) and other parties, including senior leadership, to help develop SE program priorities, set goals, and then coordinate implementation across the Office. Provides staff leadership and direction by performing substantive activities related to the planning, development, administration, execution, and coordination of activities associated with the development and management within the SE review programs scope of responsibility.

- Serves as a point of contact (POC) who helps manages the flow of information relevant to SE program.
- Provides technical advice and consultation to the OS/ELT, and other management officials on quality policy strategy, plans, priorities, and significant problems/issues related to reviews.
- Facilitates updates to reviewer resources repository for the SE program.

- Identifies barriers to progress, including gaps in communication, and works to resolve them.
- Develops recommendations for program improvements to address recurring challenges.
- Coordinates with appropriate subject matter experts and facilitates program-level decisions as needed.
- Collaborates with experts within multiple scientific disciplines to ensure pertinent information is disseminated in a timely and appropriate manner.
- Promotes communication between all relevant parties.
- Drafts communication plans for the SE program.

Desired Knowledge and Skills:

The ideal candidate will exhibit a willingness and ability to quickly get up-to-speed on all the key, ongoing activities in application review programs and understand the roles of all parties involved. To be effective, the candidate will be highly organized and have a solid understanding of the relevant scientific and policy stemming from recent application decisions. The position may entail assigning tasks and directing work, so the ideal candidate will feel comfortable interacting with various groups in the office, including the executive leadership team.

- Mastery of principles and limitations of biological or physical scientific theories, concepts and methodologies. Skill in applying this knowledge in independently carrying out research or review projects.
- Highly organized and have a solid understanding of the relevant scientific and policy stemming from recent SE decisions.
- Exceptional skill in leading, planning, and managing projects and resources to accomplish a variety of concurrent activities.
- Recognized as an expert in developing policies and program objectives.
- Expert knowledge of FDA regulations, statutory authorities, policies, and processes.
- Excellent organizational skills.
- Excellent oral and written communication skills.
- Exceptional interpersonal relationship skills and ability to collaboratively lead teams (e.g., mentor and train staff, maximize each person's contributions, reconcile divergent viewpoints, and maintain harmonious working relationships).

Application Procedure:

This detail opportunity is open to all qualified candidates at the GS-14 grade levels or Commissioned Corps officers.

Interested applicants should submit a copy of their resume, most recent copy of SF-50, transcripts, and statement indicating the reason for interest in being considered for this detail via email to:

<u>CTP-Recruitment@fda.hhs.gov</u> Center for Tobacco Products, FDA Detail is reimbursable. Travel Expenses will not be paid.

Candidates must express interest by May 17, 2023

Supervisory concurrence is required in order to accept a detail (it is NOT required to apply)
*This is not an official vacancy announcement under the Merit Promotion System