REIMBURSABLE DETAIL
Center for Tobacco Products

The Center for Tobacco Products (CTP), Office of Science (OS) is offering a Detail opportunity for a **Supervisory Regulatory Health Information Specialist (Deputy Director), GS-601-15.** Applicants at the GS-14 and GS-15 grade levels are encouraged to apply. The detail is available immediately for a period of 120 days. More than one selection may be made on a rotational basis. PHS Commissioned Corps Officers may apply. A temporary promotion will be considered.

Bargaining Unit Status:	Non-Bargaining Unit Position
Position:	**Supervisory Regulatory Health Information Specialist (Deputy Director), GS-601-15**
Office Location:	FDA, Center for Tobacco Products Office of Science Calverton Tower 11785 Beltsville Drive Beltsville, MD 20705 **Work will be done remotely.**
Opening Date:	**Monday, January 25, 2021**
Closing Date:	**Friday, February 5, 2021**
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 want to make a difference to improve public health. These positions are ideal for individuals who wish to play a critical role in the organization and would enjoy the challenge of handling a fast-paced and high-impact assignment.

Duties Include:

The incumbent serves as a Supervisory Regulatory Health Information Specialist in the Office of Science (OS), Division of Regulatory Science Informatics (DRSI) and is responsible for strategic and operational planning of all aspects of information systems and programs that support regulatory science and review objectives in the OS. As the Deputy Director, the incumbent shares fully with the Director in providing executive leadership and managerial direction to Informatics staff responsible for business and system needs analysis, data analysis, data quality, and report generation for Office and Center upper management; training and support to scientific staff in the use of information management tools; and project management support for regulatory IT systems development. With the DRSI Director, the incumbent provides leadership, supervision, oversight and direction to staff responsible for managing Office-led and Agency-wide projects, identifying Office information management and reporting requirements, and ensuring data quality of the regulatory health information systems.

- Provides leadership and direction to computer scientists, informatics and regulatory specialists, IT and administrative staff through subordinate supervisors.
- Directs personnel actions, career development and employee counseling.
- Provides expert advice, assistance and leadership to Office and Center management in the evaluation, assessment and improvement of review systems with an overarching goal to promote the use of electronic data submission, analysis and storage.
- Plays a key role in the Center's Data Governance activities and represents the Center on Agency Data Standards initiatives.
- With the Director, serves as the Office's information technology expert for regulatory science and research information pertaining to products regulated by the Center. The incumbent analyzes current data and projects, future regulatory informatics capabilities and needs; researches problems and consults with other professionals both within and outside the Center, Agency and the Federal government as necessary.
- Directs modifications of the existing systems based on user needs and represents user interests in the development of new information systems. Evaluates needs of the Office to effectively implement a managed review process and various provisions of the Family Smoking Prevention and Tobacco Control Act. This includes supporting scientific research and developing an information technology infrastructure to support knowledge management.
- Utilizing a thorough understanding of Office programs and scientific information needs, develops new business requirements to meet the Office's regulatory informatics needs and serves as the Office's principal liaison to staff in other Offices and at the Agency level who direct development of scientific information technology systems.
- Provides advice and assistance to Office and Center management concerning regulatory science informatics requirements, including the use of data standards and review tools to leverage information and data submitted in submissions to make regulatory decisions.
- Performs other duties as assigned.

Desired Knowledge and Skills:

- Expert knowledge of the analysis, design, implementation, and evaluation of regulatory and health information and data systems used in the management of the regulatory review and regulatory science research processes and in the assessment of public health outcomes and risks associated with the use of tobacco products.
- Ability to analyze health data, develop and formulate health data policy, advise agency management on health data issues, public health risk, and ensure compliance with Federal laws governing the flow of health information that includes the safeguarding the privacy and confidentially of health information.
- Knowledge gained from a degree in a health or allied science field to formulate knowledge management and data management and analysis solutions.
- Comprehensive knowledge of the Food, Drug and Cosmetic Act, Chapter IX Tobacco Products and related legislation, regulations, policies, and guidance.
- Thorough knowledge of a wide range of principles, practices, techniques, and current research developments related to the regulatory science issues impacting public health-based regulation of tobacco products and the ability to integrate science and regulatory principles to guide division staff in approaches to identifying and developing informatics solutions to support office programs.
- Mastery knowledge in planning for long-range projects and thorough understanding of Office programs and scientific information needs to develop new business requirements to meet the Office's regulatory informatics needs, and to serve as the Office's principal liaison to staff in

other Offices and at the Agency level who direct development of scientific and regulatory information technology systems.
- Ability to supervise and demonstrated leadership experience; Supervisory, Team Lead or project lead experience is preferred.
- Ability to communicate and foster cooperation among teams and across disciplines.

Application Procedure:

Supervisory concurrence is needed to accept the detail; it is not required in order to apply.

The Detail opportunity is open to all qualified FDA employees at the GS-14 and GS-15 grade levels or Commissioned Corps Officers (O-5, O-6).

Interested applicants should submit a copy of their resume, most recent copy of SF-50, a copy of your unofficial transcript(s), and statement of interest via email to:

Gretchen Winand
Office of Management, Center for Tobacco Products, FDA
Gretchen.Winand@fda.hhs.gov

Please indicate in the subject line of the email:
Detail: CTP, OS, Supervisory RHIS (Deputy Director), GS-601-15

A degree in a health science or an allied scientific field is required.

Detail is reimbursable.
Travel expenses will not be paid.

To be considered for this opportunity, all requested documentation must be submitted by the date this announcement closes, **February 5, 2021**.

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