REIMBURSABLE DETAIL
Center for Tobacco Products
Office of Science

The Center for Tobacco Products (CTP), Office of Science (OS) is offering a detail opportunity for a Supervisory Regulatory Health Information Specialist, GS-601-14. The Detail is available immediately for a period of 90 days with the possibility of extension up to 30 days. A temporary promotion will be considered. Multiple selections may be made from this announcement. Applicants at the GS-13 and GS-14 are encouraged to apply.

Bargaining Unit Status: Non-Bargaining Unit Position

Office Location: FDA
Center for Tobacco Products
11785 Beltsville Drive
Beltsville, MD 20705
(Currently 100% Telework)

Opening Date: **July 1, 2021**

Closing Date: **July 12, 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 really want to make a difference and improve public health. This regulatory health information specialist position is ideal for someone who wants to have a critical role in the organization and would enjoy the challenge of supervising others in managing data science, data analysis, data reporting, data visualization, data model, and data architecture.

Duties include:
The detail will be located in the Data and Systems Branch within the Division of Regulatory Science Informatics (DRSI). The primary role of the division is to strategically develop IT solutions to support the regulatory and scientific reviews of tobacco products for the Office of Science. Duties for this position may include:

- Leads and supervises a team of individuals who manage data science, data analysis, data reporting, data visualization, data modeling, and data architecture in regulatory information systems that support tobacco product review, and other OS business functions that require knowledge of information management, automated processes and data management.
- Analyzes current and projected data needs of regulatory reviewers, supervisors, and managers to determine scientific and regulatory business requirements for development and enhancement of information systems and reports generated from the systems to include directing activities with appropriate agency and contractor personnel.
- Provides management reports and presentations on various aspects of products regulated by the Office.

- Provides written analysis of the data model and data architecture to determine areas needing improvement and provide recommendations to improve the data model and data architecture in the regulatory information systems.
- Provides direction and oversight of computerized regulatory information/data pertaining to products regulated by the Office.
- Provides analysis of regulatory review and scientific health information/data needs of the Office in relation to existing capabilities for providing information to OS staff on a variety of topics associated with the regulatory review process, research, and knowledge management.
- Provides advice and is responsible for coordinating the development and distribution of periodic and special reports pertaining to product review status and other matters related to various regulatory review, research and knowledge management activities performed by the Office.
- Fosters collaboration and communication within the teams, branches, Division of Regulatory Science Informatics and Office of Science.
- Provides day-to-day leadership and guidance; plans and assigns work.
- Performs other similar duties as assigned.

Desired Knowledge and Skills:

- Knowledge of a wide range of principles, practices, techniques, and current research development in data science, data analysis, data visualization, data reporting, data modeling and data architecture.
- Knowledge of the information contained in the database systems and the interrelationships between various data elements in the Office's information systems and the ability to use that knowledge to: 1) evaluate the systems; 2) produce comprehensive reports concerning products regulated and business activities of the Office; and 3) design and improve the data model and architecture of the systems.
- Knowledge of the regulatory review process for the products regulated by the Center and how the various scientific disciplines interrelate with each other to recognize the need to change data elements to reflect management needs.
- Knowledge of legislation and regulations affecting the Center's and FDA's review process to identify and satisfy data reporting and IT needs.
- Knowledge of the scientific/medical material in the product submissions regulated by the Office to identify specific data needs and to identify areas where the reporting capabilities of data systems need to be enhanced or modified.
- Excellent organizational skills.
- Effective verbal and written communication skills.
- Ability to foster accountability and commitment to the mission of the Division.
- Ability to lead and supervise a team.

Application Procedure:

This detail opportunity is open to all qualified candidates at the GS-13 and GS-14 grade levels and Commissioned Corps Officers equivalent. A temporary promotion may be available.

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

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

To qualify for this detail, you must have a Bachelor's or higher degree in an academic field related to health sciences, allied sciences, or the medical field.

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

Detail is reimbursable.
Travel Expenses will not be paid.

The employee will work remotely under maximum telework until further notice.

Candidates must express interest by July 12, 2021.

Supervisory concurrence is required to accept a detail; it is NOT required to apply.

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