REIMBURSABLE DETAIL
Center for Tobacco Products

The Center for Tobacco Products is offering Detail opportunities for a **Lead Regulatory Health Information Specialist, GS-601-14**. The Detail is available immediately for a period up to 120 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

Opening Date: **August 22, 2019**
Closing Date: **August 28, 2019**

Area of Consideration: **FDA -Wide**
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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 position is ideal for someone who wants to have a critical role in the organization and would enjoy the challenge of IT software and systems development, operations and maintenance, systems design and support, data management, data analysis and data visualization.

Background:
This position is located in the Division of Regulatory Science Informatics, Office of Science (OS). As a Lead Regulatory Health Information Specialist, the incumbent leads a team that supports regulatory science and is responsible for the overall integrity and accuracy of regulatory and scientific information in the Office. 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 a team of individuals who manage regulatory information systems that support tobacco product review, mastery knowledge management, and other OS business functions that require mastery knowledge in information management, automated processes and data management.
- Analyzes current and projected needs of regulatory reviewers, supervisors and managers to determine 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
- Leads the team in: identifying, distributing and balancing workload and tasks among employees in accordance with established work flow, skill level and/or occupational

specialization; making adjustments to accomplish the workload in accordance with established priorities to ensure timely accomplishment of assigned team tasks; and ensuring that each employee has an integral role in developing the final team product.

- **Desired Knowledge and Skills:**
  Mastery of a wide range of analytical and evaluative theories, database analysis, methods and procedures applicable to evaluating the effectiveness of the Office's information management and reporting mechanisms for determining appropriate enhancements/improvements to the systems.
- Expert knowledge of the information contained in the database systems and mastery of 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) provide quality assurance of the data and reports generated from the systems.
- Mastery of the regulatory review process for the products regulated by the Center to identify the need for specific tools or IT support mechanisms.
- Expert knowledge of legislations and regulations affecting the Center's and FDA's review process to identify and satisfy data reporting and IT needs.
- Extensive 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.
- Advanced knowledge and skill of SharePoint, or similar platforms, to facilitate collaborative efforts and knowledge management including, but not limited to, developing, managing content and testing functionality to provide direct, hands-on support of CTP's SharePoint sites for scientific review programs and related activities.
- Knowledge of how the various scientific disciplines included in the Office's regulatory responsibilities interrelate with each other to recognize the need to change data elements to reflect management needs.
- Excellent organizational skills, and effective communication skills both verbal and written.
- Ability to foster accountability and commitment to the mission of the Division.
- Ability to lead a team.

Application Procedure:
This detail opportunity is open to all qualified candidates at the GS-13 to GS-14 grade level or 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/Division of Human Capital
Gretchen.Winand@fda.hhs.gov

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

Detail is reimbursable.
Travel expenses will not be paid.

The employee will work from the CTP Office of Science duty station in Beltsville, MD.

Candidates must express interest by August 28, 2019.

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.