

REIMBURSABLE DETAIL
Center for Tobacco Products
Office of Science

The Center for Tobacco Products (CTP), Office of Science (OS) is offering a detail opportunity as a **Lead Regulatory Information Specialist, GS-301-14**. 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

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 systems and business process modernization, scientific computing, strategic planning, customer support and IT project management.

Duties include:

The detail will be located in the Informatics Services Support Branch (Branch Two) within the Division of Regulatory Science Informatics. 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 service desk support services.
- Analysis of current and projected IT capabilities for regulatory and scientific review in relation to existing capabilities for providing information to Office staff on a variety of topics associated with the IT solutions for the regulatory review process, research and knowledge management.
- Serves as an authority in the management of large and complex software application development efforts providing the technical expertise for the IT program development and the policies associated with it.
- Provides the planning, organizing, and execution to completion various analytical studies identifying the need for advance Center and/or Office-wide information systems

involving major system deliverables and software performance and ensuring compatibility with existing system configuration.

- Facilitates rapid response executive care, training, requirements gathering, software procurement, IT portfolio management, reporting, policy management, business analysis and other customer service support activities to Office staff.
- Provides direction and oversight over the system(s) for the receipt, triaging, assignment, scheduling, tracking and reporting of projects and activities throughout the division.
- Fosters collaboration and communication within the teams, branches, Division of Regulatory Science Informatics and Office of Science.
- Performs other similar duties as assigned.

Desired Knowledge and Skills:

- Mastery of a wide range of analytical and evaluative theories, methods and procedures applicable to evaluating the effectiveness of the Office's information management and determining appropriate enhancements/improvements to the systems.
- Expert knowledge of a wide range of analytical and evaluative theories, database analysis, methods and procedures applicable to evaluating the effectiveness of an IT system, tool or reporting mechanism and critical thinking to determine appropriate enhancements/improvements where necessary.
- 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.
- Expert knowledge of innovative activities and methods for developing new IT services or products or improving existing services or products.
- Comprehensive, in-depth knowledge of the regulatory review process for the products regulated by the Center to identify the need for specific tools or IT support mechanisms.
- Complete and thorough knowledge of legislations and regulations affecting the Center's and FDA's review process.
- Excellent organizational skills, and effective communication skills both verbal and written.
- Ability to produce thorough, written analysis on the evaluation and assessments of IT solutions, business processes, policies, guidance,
- 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

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.