REIMBURSABLE DETAIL
Center for Tobacco Products
Office of Science

The Center for Tobacco Products, Office of Science is offering Detail opportunities for **Lead Medical Officer GP-602-15.** Applicants at the GP-15 levels are encouraged to apply. The Detail is available immediately for a period of 120 days.

Bargaining Unit Status: Non-Bargaining Unit Position

Office Location: FDA
Center for Tobacco Products
Office of Science
11785 Beltsville Drive
Calverton, MD 20705

Opening Date: **February 19, 2020**
Closing Date: **March 6, 2020**

Area of Consideration: **HHS-Wide**

The CTP Office of Science, Division of Individual Health Science offers a fast-paced, dynamic environment and an opportunity to work with dedicated, energetic people who 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:

Medical Officers serve as scientific experts in the health implications of tobacco product use. This includes, but is not limited to, evaluation and analysis of clinical studies, product use initiation and cessation, adverse health impact resulting from tobacco use, and the results of medical care on the morbidity and mortality of tobacco users. The incumbent establishes top level strategy, objectives, and performance measures for assigned projects and must be able to prioritize work. Assignments include novel problems that are handled by planning and carrying out either individual projects or major studies. Work includes complicating factors, e.g., the accepted solution of them may be in direct conflict to the accepted solution of another. The incumbent provides expert advice and assistance to scientists and officials on wide range of matters and is responsible for the sustained progress of the projects in accordance with scope, cost and scheduled baseline as well as the protection of human subjects and environmental soundness.

As a scientific expert, medical officers keep up with literature and scientific developments in the field of tobacco use; develop research projects to fill gaps in knowledge related regulatory decisions; provide scientific support in developing and/or updating guidance and policy; review documents submitted for regulatory action; advise CTP and CTP-OS management on issues

related to scientific subject matter; and provide verbal and written responses on all of the above. Additionally, medical officers develop new concepts, methods, and strategies for obtaining and using data on the major medical and health risks associated with tobacco use and provide medical and epidemiological expertise in the design and implementation of difficult studies.

Medical Officers review a wide range of tobacco product submissions received from industry to determine adequacy of the results. The incumbent demonstrates technical leadership by

- Interpreting complex clinical aspects of new tobacco applications
- Reviewing study results and providing recommendations
- Interpreting clinical data and, if needed, performing additional analysis of data submitted to tobacco product applications
- Preparing a comprehensive synopsis of reviews of tobacco product submissions with recommendations/acceptance/rejections of sponsor proposals
- Developing and implementing policies and recommendations for the conduct of clinical studies
- Conduct literature studies to assure a good understanding of current practices in the areas of clinical studies
- Performing other duties as assigned

As a Lead Medical Officer:

- Is responsible for ensuring that the organization's strategic plan, mission, vision and values are communicated and integrated into the team's strategies, goals, objectives, and work; communicates to the team milestones.
- Coaches the team in the selection and application of appropriate problem-solving methods and techniques;
- Leads the team in identifying, distributing, and balancing workload among employees; arranging for team member training; monitors and reports on the status and progress of work;
- Serves as coach and facilitator in coordinating team initiatives, policy implementation, and consensus building;
- Prepares reports and maintains records of work accomplishments and supporting information;
- Represents the team in dealings with the supervisor and manager to obtain resources and secure information for decisions;
- Reports to the supervisor on team and individual work accomplishments, problems, and work processes, including individual and team training needs;
- Represents the team consensus and convey the team's findings;
- Reports to the team on progress in meeting team milestones and deadlines for completion of assignments;
- Applies a wide range of qualitative and quantitative methods to analyze and improve team effectiveness;
- Leads the team in assessing its strengths and weaknesses;
- Informs the supervisor of team and individual performance, management issues and problems, and recommends corrective actions.

Desired Knowledge and Skills:

Knowledgeable in state-of-the-art areas of clinical medicine and research (such as the use of surrogate markers of exposure and disease). The incumbent also compiles data to prepare presentations to support Agency recommendations on scientific issues.

Must possess a mastery of the theories, principles, and methods of research in medicine and associated scientific disciplines sufficient to allow employee to review a variety of complex industry applications to apply new scientific and technological developments to novel and critical problems which cannot be solved by the use of conventional methods; and to extend and modify approaches precedents and methods in order to resolve and prevent obscure and unprecedented problems in the area of tobacco products.

Mastery includes a thorough knowledge of recent developments in medical science and associated scientific disciplines; applicable Agency laws, regulations, policies, procedures and guidelines; scientific information on unexpected side effects, injury, toxicity or scientific reactions associated with the regulated and related products.

Must possess ability to recognize the need for and then develop new procedures to solve critical or novel problems or to perform more refined analyses.

Must have ability to advise others in application of Agency rules, regulations and procedures.

Must demonstrate skill to identify problems, gather information, draw conclusions, recommend solutions, prepare papers and reports for publication, provide advice to other scientists, and negotiate acceptance and implementation of recommendations.

Must have ability and skill in accomplishing work through others when necessary and have communications skills sufficient to draft papers or guidance documents for publication and provide advice to other scientists.

Scientific knowledge of tobacco products and tobacco regulation is desired but not required. Additionally, knowledge or expertise in tobacco-related illnesses and/or diagnosis and treatment of tobacco-related medical conditions is desired.

Application Procedure:
The detail opportunity is open to all qualified candidates at the GP-14 grade level or Commissioned Corps Officers.
Interested applicants should submit a copy of their resume, most recent copy of SF-50, and statement of interest via email to:

Rebecca Martin
Program Analyst
Office of Management/Human Capital Team
Rebecca.Martin@fda.hhs.gov

Detail is reimbursable.
Travel Expenses will not be paid.

Candidates must express interest by March 6, 2020.
***This is not an official vacancy announcement under the Merit Promotion System**