

Consumer Safety Officer GS-0696-12/13 - Provides a focal point within the Food Drug Administration (FDA) to whom all levels of FDA personnel may turn for authoritative guidance and consultation regarding inspection and investigating methods and procedures necessary to accomplish compliance, enforcement, and regulatory objectives, participates as a subject matter specialist in the onsite evaluation of field activities, identifies areas which warrant study or improvement and prepares reports to ensure optimum efficiency and resource utilization, reviews special and unusual problems submitted by various Center/Offices and provide authoritative guidance to the resolve the issues causing the problems, conducts research into legal precedents and legislative history of the Acts enforced by FDA, prepares position papers for top FDA managers based on such research, drafts responses to correspondence from within and outside the agency concerning FDA regulated products, provides support to agency task forces establishing new or receiving regulations procedures and programs having nation or international impact.

- Basic Requirements - Degree: that included at least 30 semester hours in one or combination of the following: biological science, chemistry, pharmacy, physical science, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields that provided knowledge directly related to consumer safety officer work. The 30 semester hours can include up to 8 semester hours in statistics or course work that included the principles, theory, or practical application of computers or computer programming. OR Possess a combination of education and experience--course consisting of at least 30 semester hours in the fields of study described above, plus appropriate experience or additional education.

Chemist GS-1320-13 - Evaluate identification and characterization of drug substance's physical, chemical, biological and mechanical properties and their impact on the drug product; evaluate manufacturing processes and facilities used by foreign and domestic manufacturers of drug substances and/or products; apply mastery of chemistry principles, practices and procedures including Process Analytical Technology (PAT) to determine the adequacy of testing for raw materials and intermediates, the control of manufacturing processes, and the testing of the finished dosage forms; participate in the facility inspections related to the evaluation of manufacturing processes and controls and in support of pre-approval and cGMP inspections.

- Basic Requirements - Possess and degree in physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by coursework in mathematics through differential and integral calculus, and at least 6 semester hours of physics. OR Possess a combination of education and experience--coursework equivalent to a major as shown above, including at least 30 hours of chemistry, supplemented by coursework in mathematics through differential and integral calculus, and at least 6 semester hours of physics, plus appropriate experience or additional education.

Project Manager, GS-0301-12/13: Develops project plans that include business needs and milestone schedules. Manage all phases of assigned projects to include requirements development, implementation, resources, tracking, and reporting. Coordinates a multi-disciplinary team of professionals in a regulatory environment. Serve as the primary point of

contact for the projects, assesses stakeholder's feedback, and recommends changes to improve the project.

- Basic Requirements: At least one year of specialized experience equivalent to the GS-11 grade level in the Federal service that included: managing segments of projects; identifying project issues and proposing solutions; and drafting project documents (e.g. project plans, standard operating procedures, statements of work, and reports).

Regulatory Health Project Manager, GS-0601-12/13: Manage drug review processes for one or more classes of drugs. Plans and coordinates team activities within the Division. Serve as point of contact for all communications concerning applications in the assigned drug classes.

- Basic Requirements: A four-year course of study at an accredited college or university leading to a bachelor's or higher degree that included a major study in an academic field related to the health sciences or allied sciences appropriate to the work of the position.

Interdisciplinary Scientist, GS-0401/0405/1320-12/13: Provide scientific expertise in the area of pharmaceuticals, and pharmacokinetics, and clinical pharmacology. Apply in depth knowledge of chemistry, biology, pharmacokinetics, physiology, clinical pharmacology/pharmacy and medical science in the review of Investigational New Drug's (IND's), New Drug Application's (NDA's). Arranges for and act as a Project Officer on extramural contracts to resolve problems encountered in the review procedures.

- Basic Requirements for Biologist, GS-0401-12/13: A 4-year course of study at an accredited college or university leading to a bachelor's or higher degree that included a major field of study or specific course requirements in biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. OR a combination of education and experience which includes courses equivalent to a major, as described above, plus appropriate experience or additional education.
- Basic Requirements for Pharmacologist, GS-0405-12/13: A 4-year course of study at an accredited college or university leading to a bachelor's or higher degree with a major in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology.
- Basic Requirements for Chemist, GS-1320-12/13: A 4-year course of study at an accredited college or university leading to a bachelor's or higher degree in physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics. OR have a combination of education and experience which includes course work equivalent to a major, as shown in A above, including at least 30 semester hours in chemistry, supplemented by mathematics through

differential and integral calculus, and at least 6 semester hours of physics plus appropriate experience or additional education.

Mathematical Statistician, GS-1529 – 11/12/13 - Provide statistical regulatory support, evaluating and suggesting changes to clinical trial protocols, statistical methods, clinical trial design/conduct issues, and analyzes data from clinical studies using specialized statistical software and general programming languages. Perform statistical reviews of marketing applications such as Biologics License Applications (BLAs), New Drug Applications (NDAs), New Animal Drug Applications (NADAs), Premarket Approvals (PMAs) and Premarket Notification.

- Basic Requirements - Degree that includes 24 semester hours of mathematics and statistics, of which at least 12 semester hours were in mathematics and 6 semester hours were in statistics.

Statistician (Statistical Analyst) GS-1530 – 9/11 - Analyze epidemiological/observational data from health records, registries, natural history studies and contract databases to answer review questions concerning the life-cycle safety, efficacy and use of regulated drugs and biologics; assists in designing and producing code for methods development under the Sentinel initiative and other related programs, including Sentinel safety queries and assists in routine surveillance studies.

- Basic Requirements - Degree that includes 15 semester hours in statistics (or in mathematics and statistics, provided at least 6 semester hours were in statistics), and 9 additional semester hours in one or more of the following: physical or biological sciences, medicine, education, or engineering; or in the social sciences including demography, history, economics, social welfare, geography, international relations, social or cultural anthropology, health sociology, political science, public administration, psychology, etc.