Product/Chemistry, Manufacturing and Controls (CMC) Reviewer

OFFICE OF THERAPEUTIC PRODUCTS (OTP)
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)
FOOD AND DRUG ADMINISTRATION (FDA)
DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Become a part of an agency that touches the lives of every American!

The FDA's Center for Biologics Evaluation and Research (CBER), Office of Therapeutic Products (OTP), is recruiting multiple Product/Chemistry, Manufacturing and Controls (CMC) Review Scientists as Staff Fellows.

The Office of Therapeutic Products (OTP) is a newly established Super Office within CBER. The mission of OTP is to promote public health through a data-driven process to provide regulatory oversight that helps ensure medical products are safe and effective. OTP oversees the development and regulation of a wide variety of biological products, including cell therapy products, tissue-engineered products, and gene therapy products, plasma protein products derived from blood and their recombinant analogues, and certain medical devices used in the production of these products. In addition to performing regulatory review of product quality, safety and effectiveness, the Super Office conducts applied scientific research related to the products that it regulates, develops relevant regulatory policies, and supports other agencies and center components involved in ensuring compliance with CBER biologics regulations.

RESPONSIBILITIES: The selected candidate will be part of a cutting-edge and fast-paced scientific and regulatory environment. As a Staff Fellow, you will have the opportunity to:

- Perform scientific review, interpretation, and documentation of product manufacturing data to evaluate the safety and quality of cell therapy products (e.g., stem cells, functionally mature/differentiated cells, cell-based cancer vaccines, cellular immunotherapies, xenotransplant cells/organs), gene therapy products (e.g., genetically modified cells, viral or nonviral vectors, genome editing, and peptide/neoantigen- and gene-based cancer vaccines), tissue engineered products (e.g. cell-seeded scaffolds, tissue constructs, 3D bioprinted tissue-engineered constructs), and/or select medical devices in regulatory submissions to the FDA.

- Contribute to guidance and policy development activities relevant to cell, gene, and tissue engineered therapies and related medical devices.

BASIC QUALIFICATIONS: This position is multidisciplinary, and applicants will be required to meet the specific qualification requirements of one of the applicable occupational series: General Natural Resources Management and Biological Sciences (RG-0401), Microbiology (RG-0403), Bioengineering and Biomedical Engineering Series (RG-0858).

ADDITIONAL QUALIFICATIONS: A Ph.D. or equivalent advanced degree (M.D., D.V.M., or Sc.D., etc.) with a strong research background in cell therapy, cell and stem cell biology, cellular immunology; cancer biology, regenerative medicine, and/or biomedical engineering; or virology, microbiology, biochemistry, molecular biology, genome editing and/or gene therapy is required. Candidates are expected to be

proficient in applying relevant scientific knowledge and research experience to support multi-disciplinary scientific and review of regulatory submissions.

PREFERRED SPECIALIZED EXPERIENCE: In addition, the candidate must have strong collaborative skills, excellent written and oral communication skills, and evidence of leadership potential. Postdoctoral experience is highly preferred. Also, knowledge of federal regulations applicable to drugs, biologics, and medical devices is helpful but not a requirement for consideration.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. *For further information, visit the U.S. Department of Education website for Foreign Education Evaluation.*

SALARY: Salary is commensurate with education/experience.

LOCATION: FDA White Oak Campus in Silver Spring, MD; alternate worksites may be possible.

CONDITIONS OF EMPLOYMENT: This position will be filled through the FDA's Staff Fellowship Program, with an initial appointment period followed by opportunities for renewal. **Applicants must be a U.S. citizen or lawful permanent resident**. No previous Federal experience is required. Appointment does not confer any entitlement to a position in the competitive service, and during the initial appointment there is no entitlement to Merit Systems Protection Board (MSPB) appeals rights.

- One-year probationary period may be required.
- Official Transcripts required.
- Background and/or Security investigation required.
- If applicant is an U.S. Citizen, males born on, or after, December 31st, 1959, must be registered with the Selective Service System or have an approved exemption. Visit the Selective Service System for more info.
- Prohibited financial interest restrictions may apply. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office webpage.
- Permanent residents are required to have resided in the United States for a **minimum of three of the last five years**.

HOW TO APPLY: If you're seeking a challenging and rewarding career opportunity, we invite you to apply today by completing the following step:

Submit a statement of interest, resume or curriculum vitae (CV), and a cover letter summarizing relevant experience and indicate your interest in cell therapy, gene therapy or tissue engineering to Manuel Manchin at Manuel.Machin@fda.hhs.gov. Full applications with all supporting documents (i.e., transcripts, names/contact information for three references, proof of U.S. citizenship or lawful permanent residency status, and other supporting documentations) should be submitted to Manuel Machin by **April 23, 2023**. Applications will be reviewed on a rolling basis. Please reference Job Code: **OTP-23-06-TER**.

ADDITIONAL INFORMATION: For additional information on CBER Careers, please visit:

- *CBER Careers*
- *Scientific Careers at the FDA*

HHS/FDA is an equal opportunity and affirmative action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or protected veteran status.

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