Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)
Office of Health Technology VI (OHT VI)
Division of Joint Arthroplasty Devices (DJAD)

Position Title: Staff Fellows – Interdisciplinary Scientist (Epidemiologist)

Location: Silver Spring, Maryland, FDA Headquarters, White Oak Campus

Application Period: Wednesday, March 2, 2022, through Wednesday, March 16, 2022

Salary Range: $89,834.00 - $138,868.00 (commensurate with education and experience)

Position Information: Full-Time – Appointment term of two (2) years, with the possibility of being extended

Who may be considered: U.S. Citizens or Permanent U.S. Residents

Introduction: The Food and Drug Administration (FDA) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective. The mission of CDRH is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States. The Office of Product Evaluation and Quality (OPEQ) is responsible for setting strategy and overseeing the Offices of Health Technology I – VII. The Office of Health Technology VI (OHT VI), using a focused Total Product Lifecycle (TPLC) approach, ensures quality end-to-end device evaluation of orthopedic devices and the consistent interpretation and application of regulatory policy and guidance.

Position Summary: The Division of Joint Arthroplasty Devices (DJAD or Division) has an immediate opening for an Epidemiologist who is dedicated to improving health outcomes and the quality of life of patients through the advancement of orthopedic medical devices. In this position, you will conduct comprehensive qualitative and quantitative analysis on the safety, effectiveness, reliability, and the impact of orthopedic medical devices across all patient populations. DJAD is seeking candidates who have strong backgrounds Biostatistics, expertise in conducting epidemiological studies and analysis, and evaluating clinical studies submitted by industry, to include design, endpoints, assessment tools, as well as patient outcome and medical device performance data. Further, candidates must be able to provide authoritative analysis of scientific data submitted to the Division for review and develop or qualify innovative tools and approaches to facilitate scientific evaluations required for orthopedic medical device reviews. This position will be filled through FDA's Staff Fellowship program.

Major Duties and Responsibilities:

As an Epidemiologist assigned to DJAD, you will:

- Plan and conduct comprehensive scientific reviews and research studies focused on the safety, effectiveness, performance, and reliability of orthopedic medical devices.

- Assess manufacturers' data to ascertain if the study designs, methodologies, endpoints, clinical claims, and performance data are supported by validated statistical analysis and treatment data.
- Engage and collaborate with patient advocacy groups, industry, healthcare, and scientific communities to ensure all relevant medical concerns will be addressed by studies with the prescribed assessment tools and endpoints.
- Serve as a consultant and a resource on cross-functional teams within the Division and Office related to the development, utilization, and interpretation of patient-based studies, in particular assessment tool determination, endpoint development, data validation, and patient elicitation methods.
- Offer guidance and feedback to Division colleagues and leadership on orthopedic medical device product reviews in the post-market space in the areas of medical device report (MDR) analyses, allegations, recalls, establishment of inspection reports, human device exemptions (HDEs)/PMA manufacturing reviews.
- Keep abreast of innovative approaches to clinical study design techniques, methodologies, and biostatics.
- Represent DJAD and OHT VI at industry, standards, FDA advisory panel, and other professional meetings to share expertise regarding study design, assessment tools, endpoints, and data collection related to real-world evidence use of orthopedic medical devices.
- Draft recommendations of national public health significance, which describe data science activities, analysis, results, and conclusions, regarding orthopedic medical device safety, efficacy, reliability, and performance, to assist in regulatory decision-making.

Educational Requirements: Applicants must possess a PhD, or equivalent science degree (e.g., ScD, DVM) in Epidemiology, Biostatistics and Informatics, Information Science, or related fields. Applicants who have completed part or all their education outside the U.S. must have their foreign education evaluated by an accredited organization to ensure that the foreign education is comparable to education received in accredited educational institutions in the U.S. For more information on Foreign Education verification, visit the U.S. Department of Education. Another listing of services that can perform this evaluation is available at the National Association of Credential Evaluation Services (NACES) website.

Desirable Education and Experience: Please document knowledge, skills, and abilities relevant to each area described below:

- Ph.D. or equivalent degree from an accredited university in Epidemiology, Biostatistics and Informatics, Information Science, or related fields. Postdoctoral research experience is preferred.
- Experience in evaluating, developing, and re-engineering clinical studies, as well as developing, applying, and validating assessment tools, endpoints, and methodologies.
- Evidence of a strong commitment to data quality, validation, and transparency.
- Ability to analyze and interpret regulatory policy and guidance to share expertise and advise leadership on highly complex and precedent-setting public health matters

How to Apply: Submit an electronic resume or curriculum vitae, cover letter containing describing why you are uniquely qualified for this position, and a copy of unofficial transcripts all in **one** document (**Adobe PDF**) to **CDRH-OHT6-Opportunities@fda.hhs.gov**, with Job Reference Code "***Epidemiologist - Interdisciplinary Scientist-001***" in the subject line. Applications will be accepted through **March 9, 2022.**

Contact Denise Townsend for questions regarding this career opportunity: Denise,Townsend@fda.hhs.gov

Additional Announcement Information

1. **COVID-19:** Due to COVID-19, the Agency is currently in an expanded telework posture. If selected, you may be expected to temporarily telework, even if your home is located outside the local commuting area. Once employees are permitted to return to the office, you will be expected to report to the duty station listed on this announcement within 45 days. At that time, you may be eligible to request to continue to telework one or more days a pay period depending upon the terms of the agency's telework policy. To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Safer Federal Workforce Task Force guidance on other Federal agency safety protocols based on vaccination status—including guidance on protocols related to masking, distancing, travel, testing, and quarantine—remains in effect.
2. **Security and Background Requirements**: All candidates must meet applicable security requirements which include a background check and a minimum of 3 out of the past 5 years' residency status in the U.S. If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security reinvestigation or supplemental investigation may be required at a later time. Applicants are also advised that all information concerning qualifications is subject to investigation. False representation may be grounds for non-consideration, non-selection, or appropriate disciplinary action.
3. **Benefits:** The Federal Government offers a comprehensive benefits package. Explore the major benefits offered to most Federal employees at https://www.usa.gov/benefits-for-federal-employees
4. For more information about Office of Science and Engineering Laboratories (OSEL) at FDA/CDRH: https://www.fda.gov/about-fda/cdrh-offices/office-science-and-engineering-laboratories.
5. Travel, transportation, and relocation expenses **will not** be paid.