Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)
Total Product Life Cycle (TPLC) Fellowship Program

PROGRAM OVERVIEW

The OPEQ TPLC Fellowship Program is designed to cultivate an agile workforce of TPLC trained employees. The fellowship is a 2-year training program for recent STEM graduates. It provides an opportunity to learn and understand the process and application of regulatory medical device policy and guidance.

PROGRAM BENEFITS

- Regulatory Knowledge
- FDA Career and Potential Job Placement
- Training support
- Federal Benefits package

ELIGIBILITY REQUIRMENTS

- STEM Majors with PhD, or MS/MA
- Recent graduates within the past 2 years
- Open to perspective graduates
- Salary is based on location and equivalent to GS-11
- Official transcripts and/or evaluation for foreign education

CORE TRAINING

The OPEQ TPLC Fellowship Program begins with 8-weeks of core training to learn about the FDA, CDRH, OPEQ, and regulatory medical device review. The fellows meet with the various OPEQ offices to learn how they are responsible for assuring patients have access to high quality, safe and effective products throughout the total product lifecycle.

The fellows participate in various trainings to include the FDA Basic Food and Drug Law (Devices), the CDRH Reviewer Certification Program (RCP), and will receive TPLC Core Competency training in Post-market, and Compliance and Quality. Fellows complete a shadowing practicum to gain insight on the role and responsibilities of a reviewer and to prepare the Fellow for rotations. To compliment the technical trainings, the fellowship program also offers professional development and skill enhancement which focuses on communication, problem solving, team building, Gallup Clifton Strengths, mentoring, coaching and much more to provide an enriching experience.

ROTATION

The OPEQ TPLC Fellowship Program includes two 11-month experiential rotations where the Fellow will be assigned to OPEQ offices for technical hands-on training and to gain medical device review experience. This experiential learning provides an opportunity for:

- **Exploration** to enrich passions, interests, skills, and networking. Learn about positions, roles and responsibilities that match interests to ignite motivation and excitement.
- **Growth** in careers by experiencing two OPEQ offices in-depth to increase capabilities and knowledge.
- **Organizational knowledge** into device regulatory review process to obtain new perspectives that will help to better perform work activities, as well as broaden outlook into career development goals.

HOW TO APPLY

If interested in TPLC Fellowship opportunity, please submit your resume and unofficial or official transcripts to: **CDRHOPEQProfessionalDevelopment@fda.hhs.gov.**

BASIC QUALIFICATIONS

Applicants must meet the specific qualification requirements of the applicable occupational series: OPM Occupational Series Qualification Requirements.

ADDITIONAL QUALIFICATIONS

To qualify as a Staff Fellow, you must: be a US Citizen; possess a doctoral-level degree from an accredited institution of higher learning, including: Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or other research doctoral-degree widely recognized in U.S. academe as equivalent to a Ph.D.. (*In limited instances non-doctoral candidates, and/or candidates with less experience may be acceptable*).

FOREIGN EDUCATION

Candidates who have completed part or all of their education outside the United States must, in order to meet qualification requirements, have their foreign education evaluated by an accredited organization to ensure the foreign education is comparable to education received in the United States. It is the responsibility of the candidate or employee to provide written proof of his/her foreign education accreditation prior to appointment or placement in a different occupational series from which placed. *For further information, visit the U.S. Department of Education - Foreign Education Evaluation.*

CONDITIONS OF EMPLOYMENT

- One-year probationary period may be required.
- This position is a **two-year** appointment and will be filled through FDA's Staff Fellowship Program
- Background and/or Security investigation required.
- Applicants who are U.S. Citizens and born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption.
- This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For additional information, please visit the FDA Ethics and Integrity Office.
- The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

EQUAL EMPLOYMENT OPPORTUNITY POLICY

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor. Equal Employment Opportunity (EEO) for federal employees & job applicants

REASONABLE ACCOMODATION POLICY

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application

process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits. Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when:

- An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job.
- An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace.
- An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events.

You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.