

Interdisciplinary Chemist Staff Fellow – (Interdisciplinary Chemist) - Orthopedic Devices

INTRODUCTION: The Center for Devices and Radiological Health ([CDRH or Center](#)), the medical devices scientific and regulatory arm of the U.S. Food and Drug Administration ([FDA](#)), welcomes applications for our Staff Fellow (Interdisciplinary Chemist) positions in the Office of Product Evaluation and Quality's ([OPEQ](#)) Office of Health Technology 6 (OHT6). These Staff Fellow positions are located in the Division of Health Technology 6C (DHT6C or Division). This Division is responsible for the total product lifecycle (TPLC) review of stereotaxic, restorative, repair, and trauma orthopedic devices.

POSITION SUMMARY: DHT6C is recruiting Staff Fellows (Interdisciplinary Chemists) to serve as orthopedic medical device reviewers. You will have the opportunity to apply your scientific knowledge and experience to conduct comprehensive qualitative and quantitative evaluations of scientific and technical data associated with orthopedic devices regulated the Center. You will collect and synthesize data from multiple sources to offer recommendations and guidance to improve the safety, quality, reliability, and performance of orthopedic medical devices. Further, you will exercise sound technical judgement and utilize science and regulatory policy knowledge in your decision-making when responding to inquiries from industry, patient and healthcare professional advocacy groups, other government entities, and stakeholders, both internal and external

DUTIES / RESPONSIBILITIES: As a Staff Fellow (Interdisciplinary Chemist), you will perform the following duties:

- Assess the safety, performance, effectiveness, and reliability of stereotaxic, restorative, repair, and trauma orthopedic devices, encompassing the total product lifecycle.
- Evaluate manufacturer's methodology, clinical studies, and scientific and technical data to determine validity and completeness of safety, effectiveness, performance, and reliability claims.
- Serve as consultants and liaisons on cross-functional teams within OHT6 and the Center.
- Provide scientific, technical, and regulatory guidance and consultation to industry, academia, private laboratory scientists, and health care professionals on the safety, effectiveness, performance, and reliability of orthopedic medical devices and/or radiological products.
- Present reviews, conclusions, opinions, and recommendations to support product advisory panels, industry, and consultants on classification actions, petitions for reclassifications, 510(k)s, PMAs, PDPs, De Novos, 513(g)s, and IDEs.
- Represent OHT6 at scientific, international standard organization, and other professional meetings, conferences, stakeholder meetings, working groups, and FDA advisory panels, as needed.

PROFESSIONAL EXPERIENCE / KEY REQUIREMENTS: To qualify for this position, you must demonstrate in your resume the necessary experience for this position, which is equivalent to the following:

- Experience in evaluating the accuracy, precision, and reliability of orthopedic devices.
- Ability to synthesize and evaluate data and information from a variety of sources, as well as the ability to identify and validate underlying causes, anticipate ancillary problems, and suggest appropriate courses of action.
- Ability to effectively interpret, assess, and communicate, both in oral and written formats, to a variety of audiences (e.g., scientists, management, and policy makers) complex scientific information, methodology, and conclusions of scientific and technical analyses.
- Draft decisions and recommendations of national public health significance, which may impact the availability of certain products due to safety, efficacy, and reliability concerns.
- Ability to build collaborative and mutually beneficial working relationships with a diverse cadre of customers and stakeholders.

BASIC QUALIFICATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: [Chemistry \(1320\)](#).

ADDITIONAL QUALIFICATIONS: To qualify as a Staff Fellow, you must: be a US Citizen, Permanent Resident, or Non-Citizen with residency status in the U.S., three (3) out of the last five (5) years; 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 for 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](#).
- 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 US. 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.
- 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. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

LOCATIONS: [FDA's White Oak Campus](#) in Silver Spring, Maryland

SALARY / BENEFITS: Salary is commensurate with education and experience. A comprehensive benefits package is offered to most Federal employees. For additional benefit information click [here](#).

HOW TO APPLY: Prior to applying, please see the following instructions:

- Submit an electronic resume or curriculum vitae and a cover letter describing why you are uniquely qualified for this job by **August 12, 2022**.
- Include Job Reference code “**2022-OHT6-DHT6C-Chemist-001**” in the email subject line.
- Email applicant package to CDRH-OHT6-Opportunities@fda.hhs.gov.
- Visit [CDRH Jobs](#) to see additional opportunities.
- Contact Denise Townsend for questions: Denise.Townsend@fda.hhs.gov

The United States Government [equal opportunity employer](#) and does not discriminate 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.