

Staff Fellow (Polymer Science)

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 from scientists and engineers to join our scientific and regulatory research teams, as Staff Fellows, in the Office of Science and Engineering Laboratories ([OSEL](#)). These positions are located in OSEL's Division of Biology, Chemistry, and Materials Science ([DBCMS or Division](#)), which focuses on a host of public health concerns in the areas of biocompatibility and toxicology, sterility and infection control, materials chemistry and performance, and nanotechnology.

POSITION SUMMARY: DBCMS is recruiting a Staff Fellow who has significant experience as a Polymer Scientist/Chemist/Materials Scientist with expertise in molecular structure-property relationships, a mechanistic understanding of absorbable/biodegradable materials, knowledge of polymer synthesis and characterization, analytical chemistry, troubleshooting and root cause analysis. We are seeking experienced scientists who have led research efforts (both fundamental and applied) and demonstrate mastery of principles, practices, and theories in the fields of Polymer Chemistry/Materials Science, possessing the credentials and expertise needed to serve as technical authorities in the scientific analysis of the safety and effectiveness of medical devices and products. Additionally, the Staff Fellow will offer authoritative analysis of scientific data submitted to the Agency and develop or qualify innovative tools and approaches to facilitate scientific evaluations required for medical device review. The position involves approximately 50% laboratory research and 50% regulatory review of applications of medical devices. The scope of the research encompasses the chemistry during the manufacturing of polymer-based medical products, as it pertains to biocompatibility upon implantation, as well as device performance, potential in situ degradation (desired/undesired), and the interplay between structure-property relationships and downstream effects.

DUTIES / RESPONSIBILITIES: The Staff Fellow will perform the following duties:

- Serve as a technical expert and authority to the Office, Center, Agency, and industry scientists related to medical device polymer chemistry/physics. This may include review of material performance, as well as of chemical characterization as it pertains to toxicological risk assessment.
- Lead and conduct regulatory science research in the realm of polymers used in medical products, develop innovative experimental approaches to assess the safety, efficacy, and performance of medical device materials, and offer evidence-based recommendations to Office leadership and regulatory review staff pertaining to findings.
- Develop and qualify scientific tools for use by stakeholders to evaluate the safety and efficacy of medical devices in the development process.
- Develop and implement robust customer and stakeholder engagement plans to identify critical gaps and high impact opportunities.
- Use project management skills to develop detailed project plans that include timelines, deliverables, milestones, resource allocation, budget and risk mitigation to ensure on time completion of project commitments.
- Assess the performance of medical device materials in support of FDA regulatory programs through the review of scientific data submitted by product sponsors. Make recommendations to lead reviewers, as well as to other regulatory review staff and Division leadership.
- Produce written products of high quality, including peer-reviewed publications that support the scientific credibility and enable the adoption and use of regulatory science tools by customers.
- Develop and evaluate Agency-wide guidelines and guidance documents concerning the data required in submissions to the Center and Agency for clearance/approval. Consult with intra-Agency standards

committees and standards-setting organizations to develop and review international consensus standards for the evaluation of medical devices.

- Serve on FDA taskforces/working groups, as needed.
- Demonstrate mindful communication to maintain transparency, outreach and collaboration, while also exercising discretion and discernment when called for.

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:

- Ph.D. or equivalent degree from an accredited university in Polymer Science, Chemistry, Materials Science or comparable biomedical disciplines. Postdoctoral research experience is preferred.
- A minimum of five (5) years of experience in providing technical expertise providing the rigorous assessment of the manufacturing, characterization, stability, and performance of polymers (including degradable polymers) used in medical devices.
- Demonstrated success in leading, developing and executing complex projects in medical device development or research to meet aggressive timelines.
- Expertise in molecular structure-property relationships, a mechanistic understanding of absorbable/biodegradable materials, knowledge of polymer synthesis, analytical chemistry, troubleshooting and root cause analysis.
- Demonstrated success in leading multi-disciplinary teams of scientists and engineers in the development and execution of strategies to address and overcome complex issues.
- Experience in interpreting and presenting complex information and concepts, in both written and oral formats to a broad audience

BASIC QUALIFICATIONS: Applicants must meet the specific qualification requirements of the following applicable occupational series: [Toxicology \(0415\)](#), [Biology \(0401\)](#), [Microbiology \(0403\)](#), [Pharmacology \(0405\)](#), [Bioengineering and Biomedical Engineering \(0858\)](#), [Chemical Engineering \(0893\)](#), [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 her/his 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 **three-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 three (3) out of the past five (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: Salary starts at \$106,823.00 and is commensurate with education and post-PhD experience.

BENEFITS: 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.
- Include Job Reference code **"2020- OSEL-DBCMS-030"** in the email subject line.
- Email applicant package to CDRH-OSEL-Opportunities@fda.hhs.gov.
- Applications with supporting documentation will be accepted through **October 19, 2022**.
- 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.