

**Chief, Office of Regulatory Affairs
Division of Allergy, Immunology, and Transplantation**

The National Institute of Allergy and Infectious Diseases (NIAID), one of the largest institutes in the National Institutes of Health (NIH), part of the Department of Health and Human Services (HHS), conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. The Office of Regulatory Affairs (ORA) in the Division of Allergy Immunology and Transplantation (DAIT) within NIAID seeks an extraordinary and transformational leader to serve as Chief of ORA.

DAIT is one of four extramural program divisions within NIAID and is responsible for 1) the management and support of basic, preclinical, and clinical research to understand, treat, and prevent immune-mediated diseases; and 2) the development of medical countermeasures against radiation/nuclear injuries.

ORA provides regulatory and quality assurance oversight to ensure that DAIT-sponsored clinical trials are conducted in compliance with all applicable national and international regulatory health authority regulations and requirements to ensure the safety of patients and the integrity of the trials.

The Chief of ORA provides strategic direction, guidance, and oversight of regulatory science affairs issues to all DAIT staff and DAIT-supported investigators. The responsibilities of the position are as follows:

- Serve as the research sponsor's authorized representative for DAIT-held investigational new drugs
- Direct and oversee the preparation and submission of regulatory health authority application submissions, reports, and correspondence
- Manage and oversee the administrative and budgetary matters of the Regulatory Management Center contract, which provides critical regulatory support to DAIT-sponsored research
- Formulate and implement regulatory and quality assurance strategies to ensure DAIT compliance with applicable state, national, and international regulations
- Monitor emerging trends and developments in the field of regulatory science in the United States and Europe to determine the potential impact on the organization
- Develop and maintain professional relationships with regulatory health authorities on the local, national, and international levels

**Qualifications
Required**

- U.S. citizen
- A doctoral degree (M.D., Ph.D.) or equivalent in the biological or medical sciences
- Expert knowledge of regulatory affairs with respect to the academic research community, pharmaceutical industry, and federal regulatory agencies

Applicants must also demonstrate the following:

- Strong strategic skills, including the ability to make complex decisions and the willingness to defend difficult positions
- Extensive knowledge of complex medical and scientific subject matter as well as evolving regulatory policy and guidance
- Experience providing effective budgetary and administrative oversight of contract research organizations

The successful candidate will possess leadership, management, interpersonal, and communication skills to interact effectively with staff, academia, private industry, and national and international research, health, and regulatory organizations.

To Apply

Interested candidates should send the following by email to NIAID-DAIT-ORACHief-Apply@mail.nih.gov:

- Curriculum vitae that includes a brief description of your responsibilities
- Bibliography
- A two-to-three-page statement describing your 1) experience and expertise in developing effective and successful regulatory strategies to navigate pathways for interactions with regulatory health authorities throughout the lifecycle of a clinical trial, 2) reasons for your interest in the position, and 3) leadership skills and experience you would bring to NIAID, including your experience promoting a diverse workforce

As the recruitment process progresses, up to three professional letters of reference may be required.

Applications will be accepted until **October 19, 2023**. For more information or questions about the position, email NIAID-DAIT-ORACHief-Apply@mail.nih.gov.

HHS, NIH, and NIAID are equal opportunity employers dedicated to diversity, equity, inclusion, and accessibility.