Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases

Director, Investigational New Drug Development and Regulatory Science

The Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) is the primary intramural center for product development-oriented research efforts to rapidly develop and translate biomedical research into new vaccines and therapeutic products. Within the VRC's Regulatory Science and Strategy Program (RSSP), VRC is seeking a director for Investigational New Drug Development and Regulatory Science (director, INDDRS) who will also serve as RSSP director. The director, INDDRS position is a senior member of the VRC scientific leadership team who provides strategic direction and oversight for the VRC's IND clinical subject safety and welfare program and is responsible for mitigating NIAID/NIH risks associated with clinical studies. The director, INDDRS serves as the legally responsible Sponsor's Authorized Representative for Food and Drug Administration (FDA) IND applications and for all associated scientific research matters as defined under U.S. law. The position directs and leads all aspects of VRC's RSSP and oversees product development strategy through the entire product lifecycle from inception, process development, product manufacturing, preclinical research assessment, regulatory strategy, clinical trials strategy, and pharmacovigilance management, as well as through IND submission and maintenance and the critical continuing relationship with the FDA. The director, INDDRS determines VRC's "priorities among priorities" for all FDA and foreign regulatory submissions including for all pre-IND and IND submissions, responses to on-going FDA queries related to IND submissions, and responses related to maintenance of the complex product development lifecycle.

Key responsibilities of the position include oversight of program budgetary resources and supervision of staff; ensuring adherence to regulatory aspects of clinical operations and Good Manufacturing Practice for investigational product development and accountability; monitoring activity pertinent to potential vaccine candidates being developed to identify scientific and experimental gaps; managing and maintaining scientific collaborations related to product assessment and development of initiatives and new projects; coordination with other agencies to secure data, reagents, expertise, clinical product component(s), and clinical trials capabilities to achieve the project development mission; providing strategic and authoritative advice and recommendations to the VRC director on optimal paths to advance clinical candidates; and conducting regulatory risk analyses to guide product down-selection for candidate vaccines and biologics (including those with pandemic/epidemic potential).

If you are ready for an exciting leadership opportunity, please see the detailed job announcement at Scientific Careers at NIH for more information about the position and how to apply.

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