

Regulatory Science Post-Doctoral Fellowship in Pharmaceutical Policy

at the Harvard-MIT Center for Regulatory Science

ABOUT THE POSITION

The Harvard-MIT Center for Regulatory Science at Harvard Medical School, in collaboration with the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, is seeking a post-doctoral research fellow to work at the intersection of regulatory science, prescription drug use, and pharmaceutical policy.

Regulatory science brings together a range of scientific disciplines to assess the quality, safety, and effectiveness of therapeutics, helping to inform regulatory decision-making over the lifecycle of drugs, devices, and vaccines. We are seeking candidates with quantitative and/or qualitative research skills to examine regulatory science issues relating to prescription drug development, clinical testing, and use, which could include the following domains:

- Biosimilar testing, regulatory approval, and utilization
- Post-FDA approval drug testing, safety programs, and “real world” use
- Rare disease drug development, testing, and use

This is an opportunity to participate in high-impact work intended for the peer-reviewed medical and health policy literatures that will inform policymaking and regulatory decision-making relating to prescription drugs.

ABOUT THE CENTERS

The Harvard-MIT Center for Regulatory Science is a partnership between Harvard, MIT, and the FDA, focused on building innovative approaches for the development and evaluation of medical products. Working across academia, industry, and government institutions, the Center promotes regulatory science through research and education programs, uniting stakeholders under a common mission: to promote optimal patient health outcomes through biomedical innovation and the availability of safe and effective treatments.

PORTAL is one of the largest non-industry funded research centers in the US that brings together investigators from the fields of medicine, law, epidemiology, and health policy to critically evaluate emerging issues on the regulation, use, and reimbursement of therapeutics. The faculty members, numerous post-doctoral students, and affiliated researchers working on regulatory science issues in PORTAL seek to clarify by collecting and analyzing rigorous, timely, and actionable data, which laws and practices best promote effective, safe, affordable, and equitable use of therapeutics.

Ameet Sarpatwari PhD, JD—the primary mentor for the fellowship—serves as the Assistant Director of PORTAL and an Assistant Professor of Medicine at Harvard Medical School. His research draws upon his interdisciplinary training as an epidemiologist and lawyer and has focused most recently on examining key trends at each stage of the drug product lifecycle that affect cost and innovation, publicly funded contributions to drug discovery and development, and physician and patient experiences with FDA-imposed post-approval safety programs.

BASIC QUALIFICATIONS

Individuals with doctoral degrees (Ph.D., M.D., Pharm.D., J.D., or equivalent) with training and/or experience in pharmaceutical health services research, pharmacoepidemiology, or pharmacoconomics

APPLICATION PROCEDURE AND REQUIREMENTS

The initial application should include:

- A curriculum vitae
- A cover letter with a description of relevant research experience, subject interests for the fellowship, and career goals.
- A writing sample (preferably a peer-reviewed publication)

Selected candidates will be interviewed and asked to provide 3 references.

POSITION DESCRIPTION

Host Institution: Harvard Medical School

Appointing Department: Harvard Program in Therapeutic Science

Research Laboratory: Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoconomics, Department of Medicine, Brigham and Women's Hospital

Location: Boston, MA

Category: Scientist

Other responsibilities: no administrative or teaching obligations

Duration of fellowship: 2 years

EEO STATEMENT

We are an equal opportunity employer, and all qualified applicants will receive considerations for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, gender identity, sexual orientation, pregnancy and pregnancy-related conditions or any other characteristic protected by law.

CONTACT

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