



## PH290: Diagnostics in Infectious Diseases: Development and Regulatory Challenges Spring 2022

Diagnostics are indispensable for clinical management and can reduce late-stage health care spending. Accurate diagnostic tests are the cornerstone of global health programs, but tests need to be approved by regulatory authorities before they can be used.

The course reviews domestic and global regulatory oversight and explores how tests are marketed around the world. Students will learn about the challenges to innovation generalizability and best practices to develop and translate a diagnostic test into clinical practice. Focused on diagnostics in infectious diseases, the course features ongoing epidemics and pandemics such as HIV, TB and COVID-19. Topics range from the role of diagnostics in global health, to the basics of regulatory approval and oversight, innovation in analytics, to best practices for bringing a test from the lab bench to domestic and global markets.

### Instructors



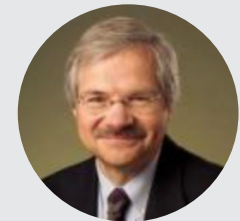
**Veronica Miller, PhD**

Dr. Miller is the Director of the Forum for Collaborative Research, a public/private partnership addressing cutting edge science and policy issues through stakeholder engagement and deliberation. She has extensive experience addressing regulatory issues in six disease areas and working with global organizations and agencies.



**Peter J. Dailey, PhD, MPH**

Dr. Dailey is a microbiologist who serves as a Senior Technical Officer for the Foundation for Innovative Diagnostics. He has held positions in public and private sectors. He has led the research and development of many infectious disease molecular diagnostics and blood-screening assays for tuberculosis, West Nile Virus, HIV, HCV, and many more.



**John Sninsky, PhD**

Dr. Sninsky is a Translational Science and Medicine consultant with a comprehensive understanding of the development and application of pioneering molecular procedures to the translation of research-grade biomarker assays into clinically-adopted diagnostic tests. Most notably, he joined the Cetus team that developed PCR.

### Course Topics at a Glance

1. Diagnostics in health care settings
2. Regulatory path for diagnostic approval
3. Infrastructures for regulation of diagnostic development
4. Research and development of diagnostics
5. Real-world applications of diagnostics across different infectious diseases
6. Implementation of diagnostics for global health programs

### Registration

1. Meet with your program advisor to discuss your course load and schedule
  - 2 unit course that meets weekly on Wednesdays 6:30-8:30PM
  - Prerequisites: Open to graduate level students; no prior course requirements
2. Go to CalCentral to register for PH290.11 (Class #: 17631)