

# Fellowship in Industry Program | 2021



## About University of the Pacific

University of the Pacific is a nationally ranked university with a long tradition of dedicated teaching, small class sizes, practical experience and vibrant residential life. The breathtaking main campus in Stockton, California is home to eight schools and colleges, with more than 80 majors and programs of study. The Thomas J. Long School of Pharmacy opened in 1955 and has a long-standing record for producing high-quality pharmacists with the option for dual degree programs (PharmD/PhD or PharmD/MS) and post-doctoral academic fellowships. Over the last nine years, average annual faculty research grants in the School totaled more than one million dollars with extensive participation in NIH and NSF grants and more than 95 percent of faculty publishing. The School touts a unique decentralized Advanced Pharmacy Practice Experience (APPE) model with seventeen regions having faculty members bolstering teaching, scholarship and service.

**Learn more at [pharmacy.pacific.edu](http://pharmacy.pacific.edu)**

## Mission

The mission of the Thomas J. Long School of Pharmacy is to prepare students for lifelong success in health careers by providing an excellent, student-centered learning environment. We aspire to develop leadership skills in our students and a strong commitment to their professions, to interprofessional collaboration, and to society. These efforts are assisted by linkages across the University of the Pacific professional and liberal arts programs. We support outstanding professional and graduate teaching, research and other scholarly activity, and services as a means of achieving our mission.



## Welcome Message from the Associate Dean of Professional Programs

Dear Prospective Fellow,

We are so pleased that you are considering the University of the Pacific's Fellowship in Industry Program (FIP) in partnership with Gilead Sciences Inc. The goal of this program is to increase industry fellowship opportunities offered through partnerships between biopharmaceutical organizations and universities on the West Coast.

At University of the Pacific, the first charter university in California, we value individualized training and focus on leadership development, which are exemplified by our partnership with Gilead. For more than 60 years, the Thomas J. Long School of Pharmacy has been training health care professionals who are problem-solvers, innovators and leaders. Our faculty dives deeper, using research to challenge the status quo of health care and education.

As an FIP fellow, you will be fully immersed in a Clinical Operations or Clinical Pharmacologist role at Gilead supporting innovative drug development. In addition, you will have opportunities to work alongside the faculty and preceptors at the University, Veteran Affairs Palo Alto Health Care System and Travis Air Force Base where you can engage in research collaboration, grant and manuscript development, teaching, student and resident mentoring and other professional development activities.

I highly encourage you to contact our FIP Director, Dr. Sachin Shah, and the exceptional team of program mentors so you can appreciate how this program can further your future success.

Best Regards,



**Allen Shek, PharmD**

Professor of Pharmacy Practice  
Associate Dean of Professional Programs  
Thomas J. Long School of Pharmacy  
University of the Pacific





## About Gilead

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. Our company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer.

Headquartered in Foster City, California, Gilead employed more than **13,000 full-time employees** in more than **35 countries on six continents** in 2020.

We have pioneered more than 25 products since our founding in 1987, including the first single tablet regimen to treat HIV and the first medicine to prevent HIV. We put that same drive and determination into our work with respect to the hepatitis C virus (HCV), which enabled us to deliver four curative HCV therapies in less than four years. We are a leader in cell therapy and we're committed to changing the way cancer is treated. Our deep antiviral knowledge, paired with our commitment to treating global health crises, also helped us rapidly advance and deliver our antiviral for COVID-19, the first treatment for COVID-19 approved by the U.S. Food and Drug Administration (FDA).







## Message from Executive Sponsor of Gilead Fellowship Clinical Operations

Dear Prospective Fellow,

Thank you for your interest in exploring Gilead's new fellowship provided in partnership with the University of the Pacific, Thomas J. Long School of Pharmacy. We are pleased to offer this inaugural program that focuses on Clinical Operations. Our post-doctoral, PharmD curriculum will offer experience in clinical development activities that support Gilead's patient-focused, science-driven drug development programs.

The Clinical Operations fellowship offers career development opportunities in the pharmaceutical industry through hands-on industry experience and guided mentorship. Upon completion of the one-year program, the fellow will have skills and training to for project management and end-to-end process management of clinical trials, including Phase 1 studies, Phase 2/3 trials, and for managing cross-functional teams, timelines, and overseeing clinical study vendors.

On behalf of Gilead, we welcome you to apply to this Program and help us discover, develop and deliver innovative therapeutics for people with life-threatening diseases.

Best Regards,



**Sandra Friborg-Beall**

Executive Director, Clinical Operation  
Gilead Sciences

## Gilead Fellowship | Clinical Operations

This one-year Clinical Operations fellowship provides in-depth exposure to Clinical Development and understanding the basic principles of clinical operations. The fellow will function as a member of Gilead's Clinical Operations team which is responsible for the execution of all Phase 1-4 Gilead clinical trials across all therapeutic areas world wide. In partnership with a cross-functional team, the fellow will ensure that all clinical trial activities are performed in accordance with applicable SOPs, company policies, regulatory guidelines, and help deliver high quality clinical data to support global registration and commercialization of new medicines.

## Activities at Gilead

The fellow will function as a clinical trial management associate and support clinical trial managers and clinical program managers on the following activities:

- Maintain internal Clinical Operations databases and document repositories.
- May serve as the key operational contact for Gilead studies, providing assistance in site selection, study implementation and ongoing coordination of study sites, either directly or via CROs.
- May serve as the key operational contact and coordinate with vendors such as central lab, IVRS for study implementation.
- May assist in set up, organization and maintenance of clinical study documentation, such as trial master files, including preparation for internal/external audits, regulatory inspections, final reconciliation and archival.
- May assist in preparation and development of protocols, informed consents, clinical study reports, monitoring plans and other study related plans.
- May lead cross-functional meetings to drive study timelines and support decision making by clinical development team.
- May assist in preparation of study training meetings of study monitors, investigators and site staff.
- May assist in study vendor budget review, contract finalization, invoice approval and budget reconciliation.

## Program Mentors



**Amy John, PharmD**  
Senior Clinical Trials Manager  
Gilead Sciences



**Michael McClain, PharmD**  
Senior Clinical Trials Management Associate  
Gilead Sciences

## Message from Executive Sponsor of Gilead Fellowship Clinical Pharmacology

Dear Prospective Fellow,

Thank you for your interest in exploring Gilead's new fellowship opportunity, provided in partnership with the University of the Pacific, Thomas J. Long School of Pharmacy. We are pleased to offer this inaugural program focusing on Clinical Pharmacology in drug development. Our post-doctoral, PharmD curriculum offers a diverse experience in clinical development functions for multiple therapeutic areas.

The Clinical Pharmacology fellow will support our research and development projects and contribute to innovative drug development at Gilead. With guidance from their mentor, the fellow will have an opportunity to design and implement integrated clinical pharmacology strategies, including modeling and simulation. The fellow will also have opportunities to contribute to project teams, to analyze data, and contribute to clinical study reports and global regulatory submissions and interactions.

On behalf of Gilead, we welcome you to apply to this Fellowship as we strive to discover, develop and deliver innovative therapeutics for people with life-threatening diseases.

Best Regards,



**Sandhya Girish, PhD**

Vice President, Clinical Pharmacology  
Gilead Sciences

# Gilead Fellowship | Clinical Pharmacology

## Activities at Gilead

The fellow, with guidance from the program mentors, will support research and development projects which will include some or all of the following:

- Design and implement a clinical pharmacology and/or modeling and simulation research project(s).
- Present the results of the research project(s) at Gilead, University of the Pacific, a local and/or national scientific meeting and/or publish them in a peer-reviewed journal.
- Serve as a Clinical Pharmacology lead for a healthy volunteer study for a small and/or large molecule project, such as food effect, drug-drug interaction, formulation bridging or bioequivalence.
- Serve as a Clinical Pharmacology representative on cross-functional project sub-teams (including clinicians, pharmacologists, biomarker experts, biostatisticians, regulatory experts), facilitating discussions of clinical pharmacology-related issues.
- Develop clinical pharmacology plans for small and/or large molecule projects and obtain buy-in from the project team.
- Author clinical pharmacology sections of documents (e.g., clinical trial protocols, investigator brochures, clinical study reports, health authority pre-meeting packages, NDAs, BLAs).

The fellow will:

- Develop hands-on modeling and simulation skills (e.g., noncompartmental, compartmental, PK/PD, and population PK modeling using softwares such as Phoenix/NonMEM, Monlix).
- Develop an understanding of ICH, FDA, EMA, PMDA and other relevant clinical pharmacology guidances and apply them in their work.
- Develop an understanding of Phase 1-4 drug development in different therapeutic areas.

## Program Mentors



**Sean Hsueh, PhD**

Senior Clinical Pharmacologist I  
Gilead Sciences



**Vaishnavi Ganti, PhD**

Senior Clinical Pharmacologist II  
Gilead Sciences



**Eileen Kim, PharmD**

Senior Clinical Pharmacologist II  
Gilead Sciences



## Brief Overview

### Fellowship in Industry Program

The University of the Pacific's Fellowship in Industry Program (FIP) was founded in 2017 with the goal of providing exceptional biopharmaceutical industry training for PharmD graduates. We strive to deepen domain specific technical skills while sharpening soft skills for all fellows. The fellows will spend 90 percent of their time at Gilead. The balance of time will be spent on professional development activities at the University.

University of the Pacific's FIP is unique for several reasons. The program:

1. Integrates pharmaceutical industry training with a blend of academia or hospital practice experiences.
2. Enhances research capabilities via engagement in the Innovative Clinical and Outcomes Research (iCOR) program.
3. Embraces the innovative culture of the San Francisco Bay Area, home to many health care startup companies.

### Program Mentors



**Sachin A. Shah, PharmD, FACC, FAHA**

Professor of Pharmacy Practice  
Regional Coordinator – Travis AFB  
Director, Fellowship in Industry Program



**Jeremy Lim, PharmD**

Adjunct Clinical Professor  
FIP Associate Director and Company Lead

## Activities at the Thomas J. Long School of Pharmacy

The fellow will have clinical faculty status at University of the Pacific, Thomas J. Long School of Pharmacy in Stockton, California.

They will be engaged in:

- Conducting research in collaboration with faculty
- Attending professional development meetings
- Developing grant and manuscript writing skills
- Advising Pacific's Industry Pharmacists Organization (IPhO) student chapter
- Mentoring rotational students in professional development and industry opportunities
- Participating in teaching activities (e.g. industry elective, research elective)

## Program Mentors



**Allen Shek, PharmD**

Professor of Pharmacy Practice  
Associate Dean of Professional Programs



**Kate M. O'Dell, PharmD, BCPS, FCSHP**

Professor of Pharmacy Practice



**Nancy N. Nguyen, PharmD,  
BCPS, AAHIVP, FCSHP**

Clinical Professor of Pharmacy Practice  
Regional Coordinator – Palo Alto



**Sachin A. Shah, PharmD, FACC, FAHA**

Professor of Pharmacy Practice  
Regional Coordinator – Travis AFB  
Director, Fellowship in Industry Program



## Select Publications from Former FIP fellows:

### Posters and Publications

- Dayal P, **Dimond C**, Yang X, Kent M, Rizzo S, Mohan D. Defining the Frequent Exacerbator Phenotype During a Pandemic in COPD. Abstract at American College of Chest Physicians (CHEST) Annual Meeting 2021; Orlando, FL 2021.
- **Dimond C**, Shah S, Dovan K, Tran B, Hsu K, Pham K, O'Dell K. Effects of Nelumbo nucifera extract on anxiety symptoms in individuals with moderate-to-severe anxiety. [Manuscript in process].
- **Liu X, Kawakatsu S**, Tran B, Tran B, Manzeno L, Shih E, Shek A, Lim J, Shah SA. Differences in Glucose Readings Between Right Arm and Left Arm Using a Continuous Glucose Monitor. Poster at American Heart Association-Scientific Sessions, 2020, Virtual Conference. (Abstract #13259). Published as a paper in Journal of Diabetes Science and Technology. <https://pubmed.ncbi.nlm.nih.gov/33955249/>
- **Kawakatsu S**, Zhu R, Zhang W, Tang MT, Lu T, Quartino A, Kågedal M. Longitudinal Placebo Response Modeling in Patients with Ulcerative Colitis. Poster at American Conference on Pharmacometrics; Aurora, CO, 2020.
- **Kawakatsu S**, Bruno R, Kågedal M, Li C, Girish S, Joshi A, Wu B. Confounding Factors in Exposure-Response Analyses and Mitigation Strategies for Monoclonal Antibodies in Oncology. <https://pubmed.ncbi.nlm.nih.gov/33217012/>
- **Kim N**, Pham K, Shek A, Lim J, Liu X, Shah SA. Differences in Glucose Level Between Left Arm and Right Arm Using Continuous Glucose Monitors. Poster at American Diabetes Association (ADA) 79th Scientific Sessions; San Francisco, CA 2019.
- Kunder R, Yeh F, Chinn L, Dash A, Lewin-Koh N, **Kim N**, Fredrickson J, Yoshida K, Chen S, Wilson M, and Wong C. Multiple Doses of an Anti-FGFR1/KLB Bispecific Antibody (BFKB8488A) are Associated with a Decrease in Hepatic Fat in Patients with NAFLD. Poster at American Association for the Study of Liver Diseases (AASLD) The Liver Meeting 2019; Boston, MA 2019.
- **Kim N**, Pham K, Shek A, Lim J, **Liu X**, Shah SA. Differences in Glucose Level Between Right Arm and Left Arm Using Continuous Glucose Monitors. Published in Digital Health. <https://pubmed.ncbi.nlm.nih.gov/33224517/>
- Pham K, **Liu X**, Shah SA, Shek A. Difference in Glucose Levels Between Continuous Glucose Monitor Brands and Application Sites. (Submitted)

### On-Going Clinical Research

- Effects of Nelumbo Nucifera Extract on Salivary Cortisol and Anxiolytic Activity in Individuals with Moderate to Severe Anxiety. PI: **Colin Dimond**, PharmD
- Effects of a natural caffeinated energy drink on blood glucose parameters. PI: **Elise Oh**, PharmD.



## Fellowship Eligibility Requirements

A candidate must:

- ☐ Be a permanent resident or citizen of the United States
- ☐ Have earned a PharmD from an ACPE accredited college of pharmacy before the start of the fellowship term

## Application Process

**Candidates must submit via email ([pharmfip@pacific.edu](mailto:pharmfip@pacific.edu)) all the following application materials by the deadline listed on the University's website:**

- ☐ Letter of intent
- ☐ Updated curriculum vitae (CV)
- ☐ Three (3) letters of recommendation emailed directly from letter writer to FIP director
- ☐ One professional writing sample that demonstrates medical writing ability
- ☐ Unofficial pharmacy school transcript emailed to FIP director
- ☐ All application materials should be addressed to:  
Sachin A. Shah, PharmD, FACC, FAHA  
Director, Fellowship in Industry Program  
Professor of Pharmacy Practice  
Thomas J. Long School of Pharmacy

**See application deadline at  
[pacific.edu/pharmacy/fellowship/gilead](http://pacific.edu/pharmacy/fellowship/gilead)**





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