



A Member of the Roche Group

# FELLOWSHIP IN INDUSTRY PROGRAM 2023





## PACIFIC The School of Pharmacy

## **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 pacific.edu/pharmacy

## 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 Genentech, 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 Genentech. 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 the Clinical Scientist or Clinical Pharmacologist role to support innovative drug development at Genentech. 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 will engage in research collaboration, grant and manuscript development, teaching, student and resident mentoring and other professional development.

I highly encourage you to contact our FIP Director, Dr. Sachin Shah, and the exceptional team of mentors so you can appreciate how deeply committed we are to your future success.

Best Regards,



Allen Shek, PharmD Professor of Pharmacy Practice Associate Dean of Professional Programs University of the Pacific



Genentech

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## **ABOUT GENENTECH**

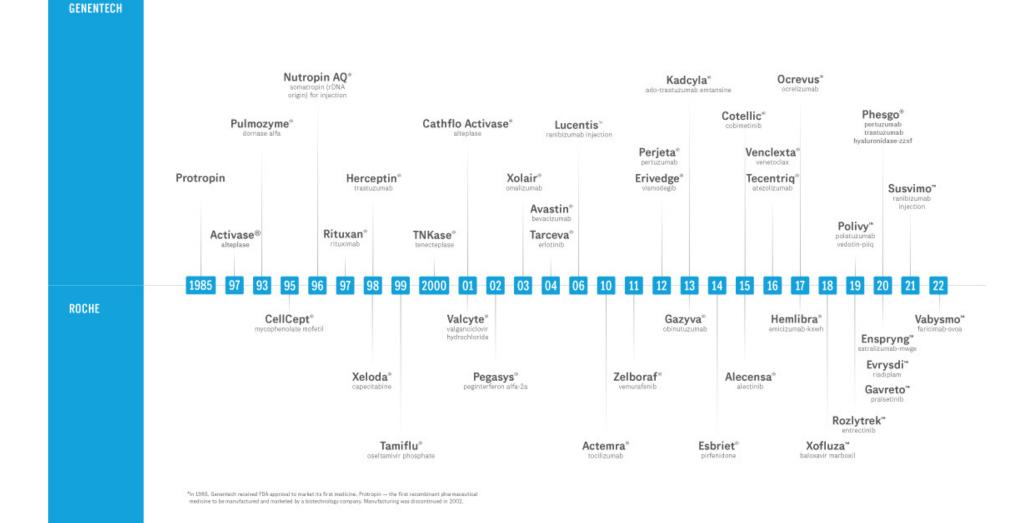
Genentech was founded in 1976, with a goal to develop a new generation of therapeutics created from genetically engineered copies of naturally occurring molecules. Today Genentech continues to use genetic engineering along with other advanced techniques to develop medicines that address major unmet medical needs for patients worldwide.

In March 2009, Genentech became a member of the Roche Group. As part of their merger agreement, Roche and Genentech combined their pharmaceutical operations in the United States. Genentech's South San Francisco campus now serves as the headquarters for Roche pharmaceutical operations in the United States. The three Roche values — Integrity, Courage, and Passion — are core to how we want to behave, as individuals and collectively as an organization.

- **Integrity** means we are consistently open, honest, ethical and genuine.
- **Courage** means we are entrepreneurial and thus take risks, reach beyond boundaries and experiment.
- **Passion** means we use our drive and commitment to energize, engage and inspire others.

These values define fundamental attributes for guiding decisions and actions leading to increased innovation and business performance.





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## MESSAGE FROM EXECUTIVE SPONSORS OF GENENTECH FELLOWSHIP CLINICAL SCIENCE - OMNI CLINICAL DEVELOPMENT

Dear Prospective Fellow,

Genentech is excited to be a part of the University of the Pacific's Fellowship in Industry Program (FIP) for Doctor of Pharmacy graduates. We know that you've worked hard on your career and, as you look forward, we know that you'll continue to be thoughtful regarding your future professional development. Toward that end, we are thrilled to offer you a unique opportunity to grow in an environment that has produced some of the best clinical trialists in the pharmaceutical industry, who in turn have produced some of the most groundbreaking medicines in the world.

As the founder of the biotechnology industry, Genentech, a member of the Roche Group since 2009, has been delivering on the promise of biotechnology for more than 40 years. Our early clinical development group based in South San Francisco offers an incredible range of clinical research training opportunities in immunology, neurology, ophthalmology, infectious diseases and other specialty areas. The early clinical development group here spans Phase 1 and Phase 2 work, and so we are in a unique position to translate discovery research into Phase 3 medicines. We have a culture that supports doing the cutting-edge science that leads to major breakthroughs and cures.

In this environment, we welcome enthusiastic and innovative doctor of pharmacy graduates who strive to transform knowledge into innovative new medicines. Because we recognize the unique backgrounds and skills that each new fellow brings to the program, our group's goal is to give you the support, training and mentorship that will assure your success. We have been part of the fellowship program and are continuing our enthusiastic commitment to developing the next generation of drug developers.

On behalf of Genentech, thank you for considering this program and I invite you to contact us if you have any questions.

Best Regards,



**Seppi Lin, MD** Vice President Head, OMNI Early Clinical Development Genentech Research and Early Development Genentech, A Member of the Roche Group

## **GENENTECH FELLOWSHIP | CLINICAL SCIENCE**

This two-year Clinical Science fellowship within Genentech's Research and Early Development (gRED) organization provides in-depth exposure to Early Clinical Development (ECD) and understanding the basic principles of clinical research. The fellow will function as a Clinical Scientist and will support Medical Directors/senior-level Clinical Scientists on a diverse set of clinical development activities.

#### Early Clinical Development OMNI (Currently recruiting)

gRED ECD OMNI's (Ophthamology, Metabolism, Neurology, Infectious Disease, Immunology) mission is to develop life changing therapies from innovative science. ECD OMNI is responsible for developing and executing strategies on Phase 1 and 2 clinical trials in healthy volunteers and patients to provide critical data for gRED non-oncology new molecular entities with respect to safety, tolerability, efficacy, pharmacokinetics, pharmacodynamics and the utility of biomarkers. The OMNI Clinical Science Fellow will have the opportunity to develop clinical research skills across various therapeutic areas.

#### **Activities at Genentech**

- Serve as a clinical science representative on cross-functional sub-teams (i.e. protocol execution, clinical, biomarkers, pharmacokinetics)
- Create, review and present clinical slides for internal (i.e. Genentech/ Roche) and external meetings (e.g. Investigator meetings, scientific congresses, advisory boards, site visits, site staff training)
- Develop understanding of Good Clinical Practice (GCP), International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), FDA, EMA, NICE and other relevant guidelines and regulations
- Draft abstracts, posters, manuscripts for scientific meetings
- Author and review of clinical documents (i.e. clinical trial protocols, clarifications and amendments, informed consents, investigator brochures, clinical study reports, investigational new drug submissions)
- Respond to inquiries from health authorities (e.g. FDA, EMA) and study site ethics committees
- Partner with the data management team to assist with the development of case report forms
- · Serve as a primary point of contact for study inquiries
- Contribute to ongoing review of the integrity of clinical trial data
- Develop understanding of Phase I-II drug development

#### Early Clinical Development Oncology (Not recruiting this cycle)

Genentech's Early Clinical Development Oncologymission is to provide the clinical leadership and skills to successfully develop novel cancer therapies and the means by which to identify the patients who benefit from them. The organization is responsible for developing strategies for and executing on Firstin-Human, Phase 1 and Proof-of-Concept oncology clinical trials. In the role of a Clinical Scientist, the fellow will gain experience in the basic principles of clinical oncology research.

#### **Program Mentors**



Chin Wong, PharmD Senior Clinical Scientist gRED ECD OMNI



Stevan Djakovic, PhD Principal Clinical Scientist gRED ECD Oncology



Jason Hong, PharmD OMNI Clinical Science Fellow 2022-2024



Sydney Stocks, PharmD Oncology Clinical Science Fellow 2023-2025



## MESSAGE FROM EXECUTIVE SPONSORS OF GENENTECH FELLOWSHIP CLINICAL PHARMACOLOGY

Dear Prospective Fellow,

Genentech's Clinical Pharmacology department is excited to be a part of the University of the Pacific's fellowship program for Doctor of Pharmacy graduates. The comprehensive training of the Doctor of Pharmacy graduate in clinical therapeutics, applied pharmacokinetics, direct patient care, and translational science provides a unique opportunity to develop and contribute as Clinical Pharmacologists in the drug development industry.

Our UOP-Genentech Clinical Pharmacology fellowship program aims to train graduates who have particular interest in Clinical Pharmacology in the areas of pharmacokinetics, pharmacodynamics, drug metabolism, quantitative pharmacology (including various types of PK/PD data modeling and "what-if" simulation approaches), as well as applying new health/IT technologies and advanced analytic approaches to support drug development. We provide the unique opportunity for trainees to work under the supervision of Senior Clinical Pharmacologists and alongside other cross-functional colleagues across Genentech as they complete this 2-year fellowship.

Our Clinical Pharmacology group based in South San Francisco offers an incredible range of training opportunities in many therapeutic areas including Oncology, Immunology, Neurology, Ophthalmology and Infectious Diseases. Our Clinical Pharmacologists are also well known among their scientific peers for their rigorous, innovative and cutting-edge approaches and we encourage them to publish and present at scientific meetings. We pride ourselves for having a culture that focuses on patients, science and our people.

On behalf of Genentech, thank you for considering this program and I invite you to contact us if you have any questions.

Best Regards,



Amita Joshi, PhD Vice President and Global Head of Clinical Pharmacology Development Sciences Genentech Research and Early Development Genentech, A Member of the Roche Group

## **GENENTECH FELLOWSHIP | CLINICAL PHARMACOLOGY** (Not recruiting this cycle)

This two-year Clinical Pharmacology Fellowship program builds on the synergy between the fellow's comprehensive Doctor of Pharmacy training and Genentech's innovation in drug development to prepare the individual for a career in the biotechnology/pharmaceutical industry. The fellow will be part of the gRED Clinical Pharmacology Department, which is responsible for applying the principles of quantitative pharmacology to enable selection of a safe and effective dose, route and regimen for small molecules and biologics. The fellow will gain drug development experience at Genentech by completing research projects in clinical pharmacology and/or modeling and simulation and collaborating with scientists across disciplines within Genentech and Roche. These experiences will potentially lead to publications and presentations at scientific conferences and give the fellow exposure to career opportunities in the biotechnology/ pharmaceutical industry.

#### **Activities at Genentech**

The Fellow will function as a Clinical Pharmacologist and will support research and development projects, which may include the following activities:

- With guidance from the Genentech and University of the Pacific mentors, design and implement a clinical pharmacology and/or modeling and simulation research project(s).
- Present the results of the research project(s) at Genentech, 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 (e.g., food effect, drug-drug interaction, formulation bridging, bioequivalence)
- Serve as a Clinical Pharmacology lead 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 with support from their mentor
- Author clinical pharmacology sections of documents (e.g., clinical trial protocols, investigator brochures, clinical study reports, health authority pre-meeting packages, NDAs, BLAs)
- Develop hands-on modeling and simulation skills (e.g., noncompartmental, compartmental, PK/PD, and population PK modeling)
- 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 I-IV drug development in different therapeutic areas

### **Program Mentors**



Katie Maass, PhD Principal Scientist Genentech Clinical Pharmacology



Sara Kim, PharmD Clinical Pharmacology Fellow 2023-2025





### BRIEF OVERVIEW FELLOWSHIP IN INDUSTRY PROGRAM

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 Genentech, Genentech Research and Early Development (gRED). The balance of time will be spent on professional development activities with the University.

Unviersity 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 which is home to many health care startup companies.

Learn more at pacific.edu/pharmacy/icor



Sachin A. Shah, PharmD, FACC, FAHA Professor of Pharmacy Practice Regional Coordinator – Travis AFB Director, Fellowship in Industry Program



Jeremy Lim, PharmD Thomas J. Long School of Pharmacy Associate Director, Fellowship in Industry Program



## **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 AND CURRENT FELLOWS

#### **Posters and Publications**

- Oh E, Owen R, Poon V, Wong K, Yoshida K. PKPD Modeling to Characterize Placebo and Treatment Effect of Omalizumab for Chronic Spontaneous Urticaria (CSU). Abstract at American Conference on Pharmacometrics (ACOP) Annual Meeting 2022; Aurora, CO, 2022.
- 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. (Under Peer-review)
- Liu X, Kawakatsu S, Tran B, Tran B, Manzenero 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/
- Sathyamoorthya M, Verduzco-Gutierrez M, Varanasi S, et al. Enhanced external counterpulsation for management of symptoms associated with long COVID. American Heart Journal Plus: Cardiology Research and Practice. January 2022.
- 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/

#### **On-Going Clinical Research**

- Time In Range Difference between Arms using Continuous Glucose Monitors in Patients with Diabetes. Pls: Allen Lat, PharmD, Sarika Mujumdar, PharmD
- Effects of a natural caffeinated energy drink on blood glucose parameters. PI: Elise Oh, PharmD.

## **PERSPECTIVES FROM FELLOWS**

"The Clinical Science Fellowship with OMNI at Genentech is a unique opportunity to learn and develop the skill set of a Clinical Scientist at the core of early clinical drug development. With the guidance of my mentors at OMNI, I have been provided a wealth of knowledge and training to become a Clinical Scientist through all stages of a clinical trial from start-up, maintenance, and close out across different therapeutic areas. As my technical skills improve, I've had the opportunity to lead key clinical science deliverables and provide input towards building and planning the strategy of a program. Genentech's OMNI and the University of the Pacific foster professional and personal growth of their fellows through available resources that support the development of fellows."



Jason Hong, PharmD 2nd Year Clinical Science Fellow

"My experiences as a first year fellow have equipped me with the tools that I need to excel my second year. These experiences, which include conducting a clinical trial from start to finish, firstauthoring a pharmacometrics-focused manuscript, and serving as the clinical pharmacology lead on a Phase 1b study, have taught me how to think scientifically, take ownership of my professional growth, and communicate effectively with other functions. I approach and conduct new projects with more confidence, efficiency, and scientific knowledge that I can attribute to the first year."



Elise Oh, PharmD 2021-2023 Clinical Pharmacology Fellow

## **PERSPECTIVE FROM GENENTECH FELLOWSHIP DIRECTOR**

"Thank you for your interest in our PharmD Fellowship in Industry Program. We're a small program, and we pride ourselves on quality. I truly believe the group of Executive Sponsors, preceptors, and mentors featured in this brochure are the industry's best. Having earned a PharmD myself, I'm passionate about training the next generation of pharmacist drug developers. I have also worked as both a clinical pharmacologist and clinical scientist at Genentech, and can speak first-hand to how a PharmD graduate's training is perfect for the pharmaceutical industry, and for success in both of these areas. A PharmD graduate brings a unique clinical perspective to the drug development team, and we look forward to teaching you a new role, but also allowing your training to make meaningful contributions immediately. Please do not hesitate to reach out if I can answer any questions about this fellowship program or Genentech."



Whitney Kirschbrown, PharmD, PhD Principal Clinical Scientist / Early Clinical Development - Oncology Genentech Research & Early Development (gRED) Genentech Fellowship Director

## FELLOWSHIP ELIGIBILITY REQUIREMENTS

A candidate must:

- $\hfill\square$  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 (<u>pharmfip@pacific.edu</u>) all the following application materials by the deadline listed on the University website:

 $\hfill\square$  Letter of intent

- □ Updated curriculum vitae (CV)
- Three (3) letters of recommendation emailed directly from letter writer to FIP director
- $\Box$  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/genentech



