

UNIVERSITY OF THE  
**PACIFIC**

Jie Du Center for Innovation and  
Excellence for Drug Development

**12 - WEEK COURSE**

# Clinical Pharmacology in Drug Development



## IMPACT

This course presents a 360-degree view of the role of clinical pharmacology in the drug development process

## WHO SHOULD ATTEND

Entrepreneurs, scientists, pharmacists and other health care professionals interested in pharmaceutical development



### Course Co-Director

**Miki Susanto Park, PhD**  
Professor, University of the Pacific



### Course Co-Director

**Krishna Devarakonda,**  
**PhD, MPharm, FCP**  
Visiting Professor, University of the Pacific



### Executive Director

**Bhaskara R. Jasti '95,**  
**PhD, MPharm, FAAPS**  
Professor, University of the Pacific



## START DATE

**January 12th, 2024**

**\$950**

12-week course, 2 hours per week

## APPLY NOW

[bit.ly/clinical-pharmacology](https://bit.ly/clinical-pharmacology)

Rolling admission until start date.



**What role does clinical pharmacology play in drug development?**

**Deepen your understanding of the development stage.**

**Develop a strategic approach to gathering and decoding real-world data.**



### **Introduction to Drug Development**

Regulatory landscape and role of clinical pharmacology.

### **Concepts of Pharmacokinetics & Pharmacodynamics in Drug Development**

### **Quantitative Systems Pharmacology & Physiologically Based Pharmacokinetics (PBPK)**

### **Early & Late Stage Clinical Development**

Design of trials (scaling, first-in-human (FIH), and the role of clinical pharmacology in early and late phase drug development.

### **Role of Pharmacovigilance & Drug Safety in Drug Development**

Monitoring safety during clinical trials and communication with FDA.

### **Assessment of Risks/Benefits**

IND/NDA/ANDA submissions and regulatory decision making.

### **Employment/Professional Opportunities for a Clinical Pharmacologist**

Right steps towards a brilliant career.

### **Clinical Studies & Clinical Pharmacology Considerations in Special Populations**

Pediatric, elderly, hepatic, and renal patient populations.

### **Case Studies: NDA (based on an SBA)**

Clinical pharmacology perspective.

### **Pharmacometrics, Modeling & Simulation, and Model Informed Drug Development**

### **Role of Biomarkers in Drug Development**

Particular reference to oncology and rare diseases.

### **Pharmacogenomics/Pharmacogenetics**

General principles with a special focus on drug safety.

We help you develop  
innovative products for  
unmet medical needs

# GUEST FACULTY



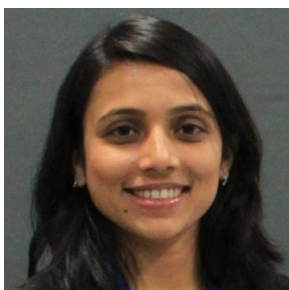
Balaji Agoram, PhD  
Vice President & Head of  
Clinical Pharmacology  
Arcus Biosciences



Mark Stroh, PhD  
Vice President & Head of  
Clinical Pharmacology  
Intellia Therapeutics



Indrajeet Singh, PhD  
Senior Director  
Janssen



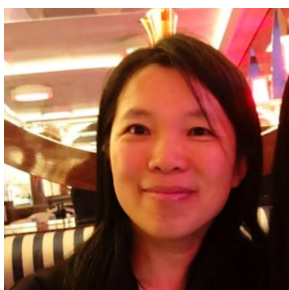
Naisargee Shah, PhD, MS  
Senior Director of Clinical  
Science and Development



Yoshiko Stowell, PhD, MS  
Head of Regulatory Affairs  
Neuron23



Ritu Lal, PhD, MS  
CEO & Co-Founder  
GEN1E Lifesciences Inc.



Li Yan, PhD  
Senior Director & Head of Clinical  
Pharmacology & DMPK  
NGM Biopharmaceuticals



Meina Liang, PhD  
Chief Technology Officer,  
President of Bioanalysis  
& Biomarkers  
Amador Bioscience



Dexter Macaranas, PharmD, JD  
Pharmacovigilance  
Clinical Scientist  
Genentech

## About the Center

The Jie Du Center for Innovation and Excellence for Drug Development promotes innovation in drug development through education, training and mentorship, while fostering collaboration between Pacific students and industrial scientists. Individuals gain skills in pharmaceutical regulation, entrepreneurship and business to prepare them for navigating the challenges associated with new ventures in drug development.

The Center offers opportunities to take one's scientific and clinical expertise and complement them with the specialized knowledge and skills that are valued in today's competitive job market.

The Center is part of University of the Pacific and is located in Stockton, California.

[LEARN MORE](#)

## About University of the Pacific

Since 1955, University of the Pacific's Thomas J. Long School of Pharmacy has been training health care professionals who are problem-solvers, innovators and leaders. The School was shaped into what it is today by the hard work, dedication and support of its charismatic faculty, staff, students, alumni and friends. Throughout the School's history, individualized, faculty-led experiential learning programs, combined with the support of a powerful alumni network, have led to student success.

## The Center will provide tools to entrepreneurs in five key areas







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**CONTACT US**

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