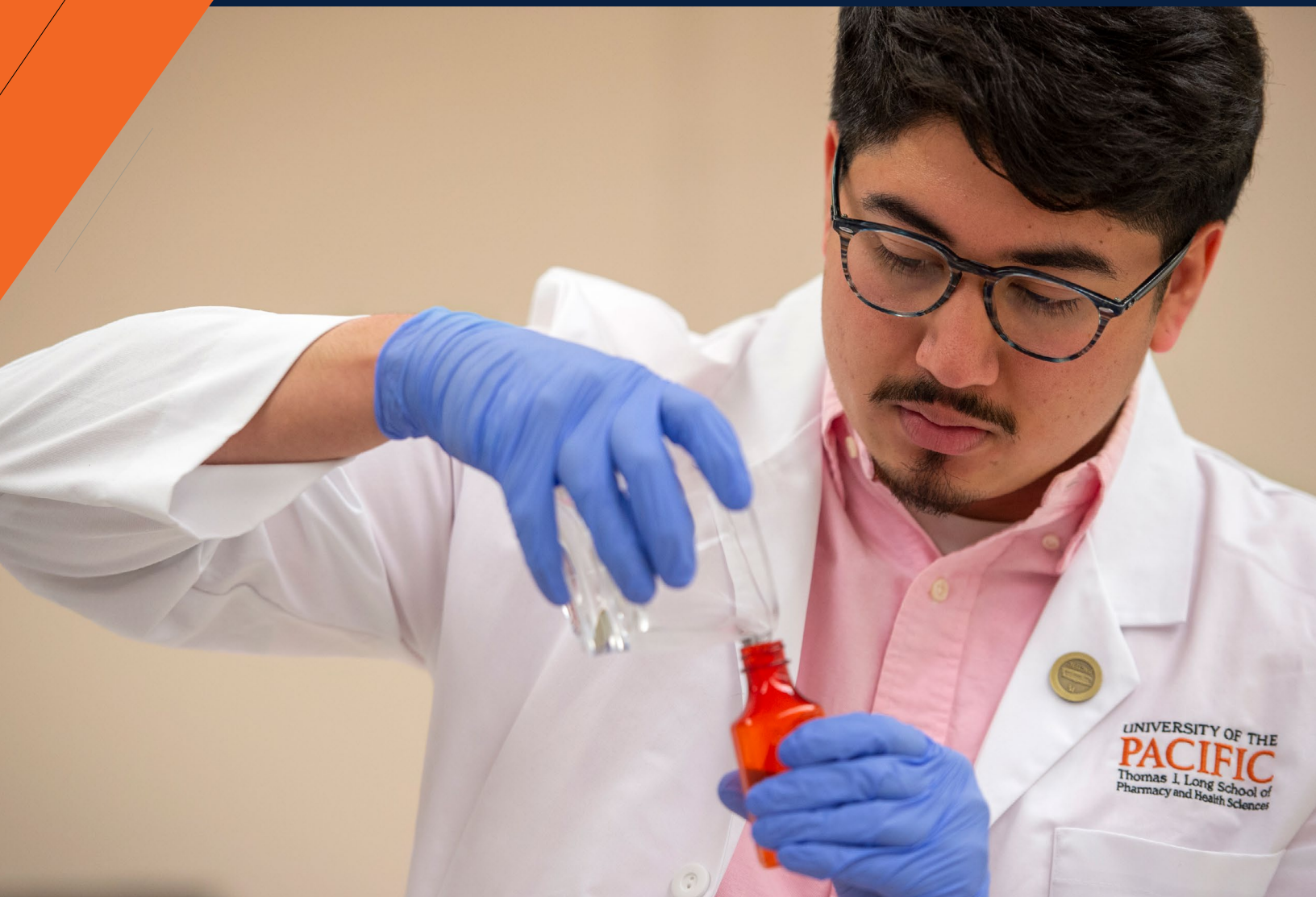
UNIVERSITY OF THE PACIFIC | Jie Du Center for Innovation and Excellence for Drug Development

13-WEEK COURSE

Regulatory Science for Drug Development Scientists

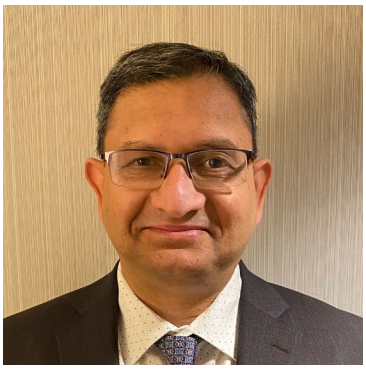


IMPACT

Understand the various aspects of drug development and regulatory guidance and harness the underlying science crucial to each stage of development

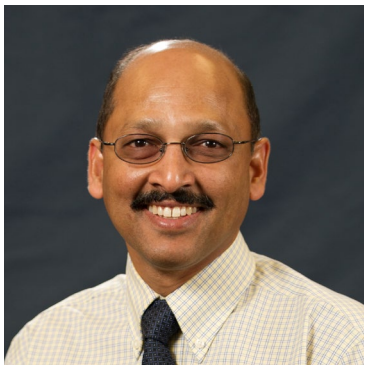
WHO SHOULD ATTEND

Entrepreneurs, scientists, pharmacists and other health care professionals interested in pharmaceutical development or are seeking to launch products



Course Director

Prasad Peri, PhD
Senior Director of Global CMC Regulatory Affairs
Teva Branded Pharmaceutical Products R&D, Inc.



Executive Director

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

START DATE

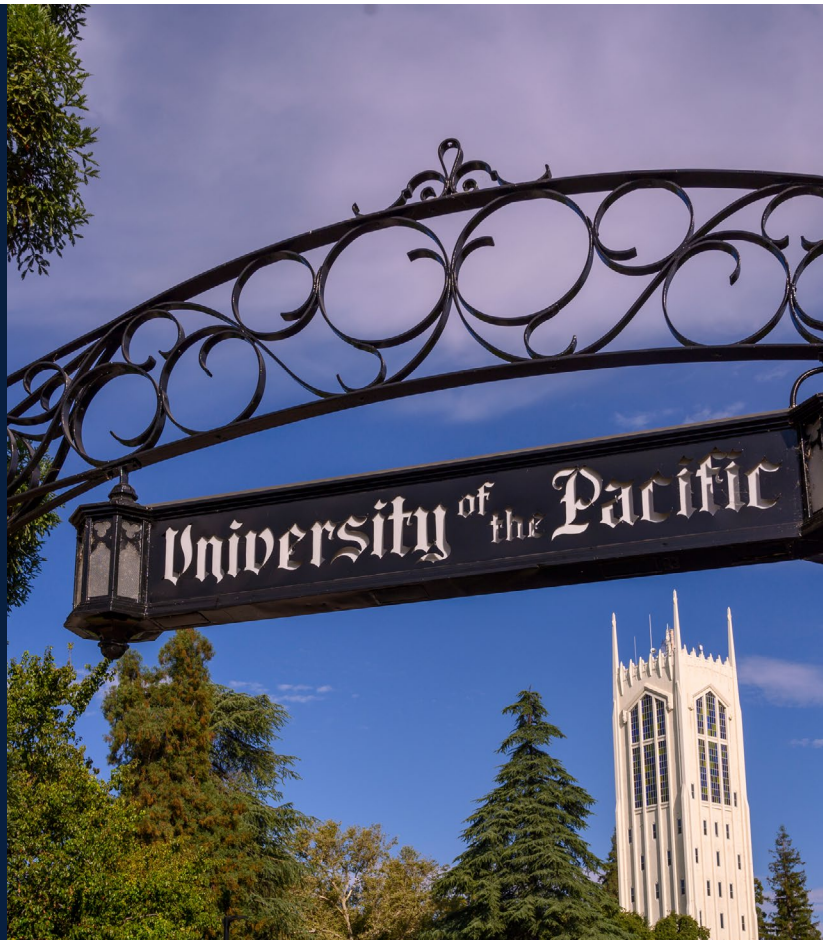
May 1st, 2025

$950

13 week course, 2-3 hours per week

Lectures on Thursdays from
4 PM to 6 PM PST

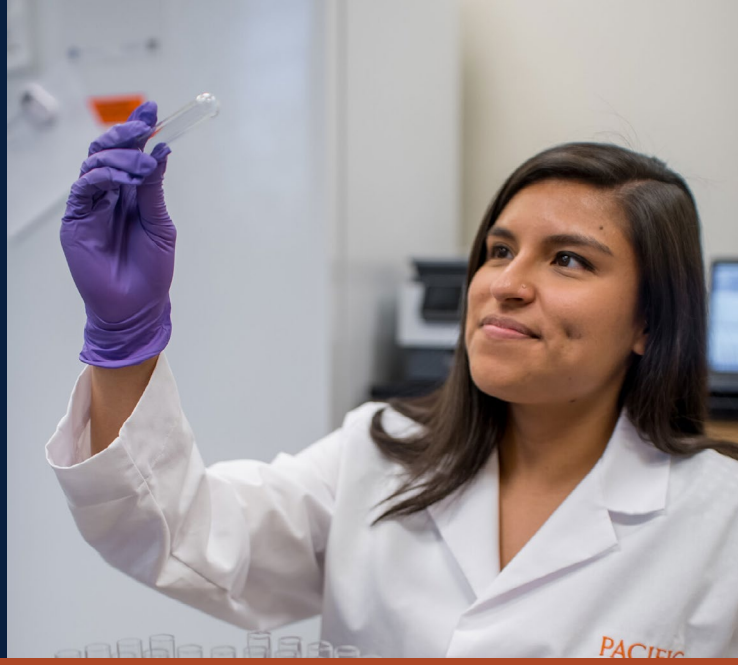
Enroll Now



How does a new drug get approved?

Learn the steps in the path to approval of a new drug product.

Decode the science behind each stage of the drug development process.



We help you develop innovative products for unmet medical needs

Differentiate IND, NDA and BLA

Understand the nuances of an Investigational New Drug Application, New Drug Application and Biologic License Application.

Understand FDA vs. EMA

Uncover the differences between the U.S. Food and Drug Administration and the European Medicines Agency regulations.

Grasp the different stages of drug development

Deepen your understanding of regulatory guidance at each stage of the drug development process.

Understand in vitro vs. in vivo

Learn the methodologies used for drug release and absorption and how to correlate them.

Contrast drug substance vs. drug product

Understand the stability of a drug substance and of a drug product. Compare the regulations for a drug substance and a drug product. Learn how to establish expiration dates.

Consider immediate release vs. modified release

Describe and differentiate the regulatory guidance on setting specifications immediate release and modified release.

Navigate production

Understand the guidance for formulation, process, scale-up and post approval changes.

Decode the life cycle management of a drug product

Navigate compliance and regulatory challenges.

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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.

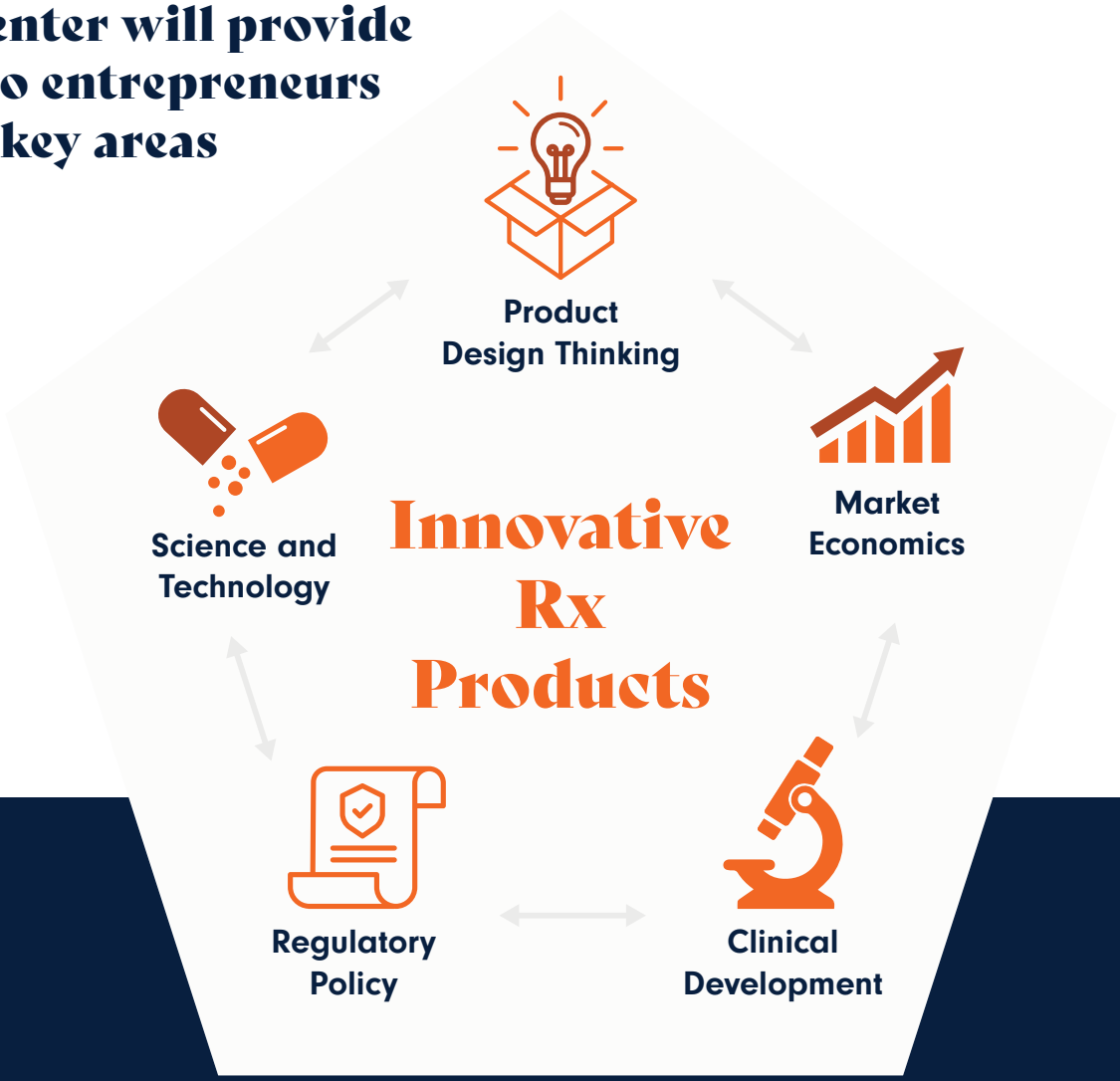
The Center is part of University of the Pacific and is located in Stockton, California.

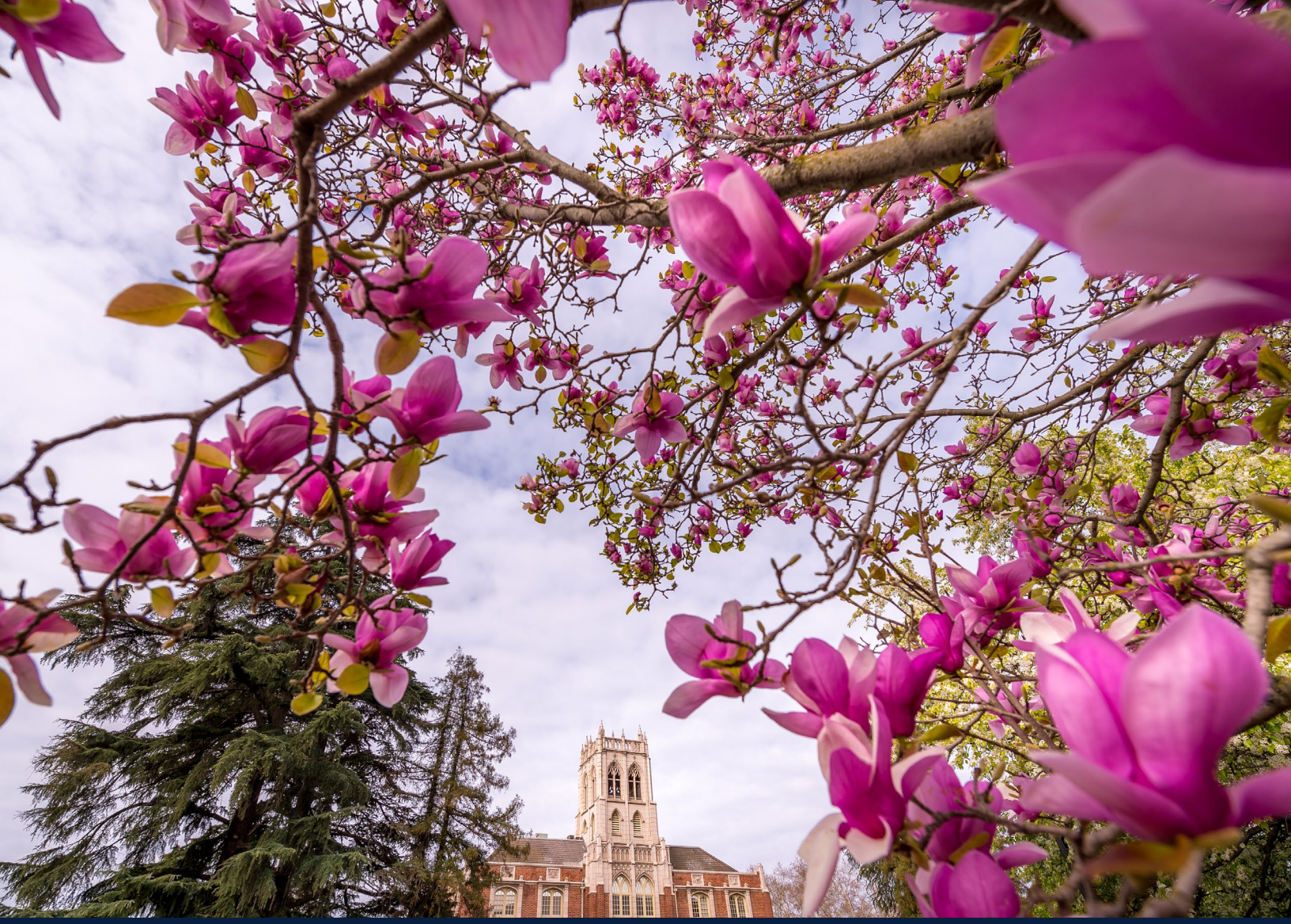
LEARN MORE

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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Innovation and
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CONTACT US

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