California Section
American Chemical Society

Women CHEMISTS Committee

All are welcome
Saturday, May 10, 2025

Title

From the Laboratory to the Market Place: The Development of a New Drug

Time
10:30 – 11:00 am
Chatting

11:00 am
Talk and Discussion

Reservation
Please visit the CalACS website www.calacs.org to register for this meeting or use Brown Paper Tickets.

RSVP here!

Please register before Thursday, May 8, 2025, 12 noon. Your email address is needed to send the ZOOM link, which will be shared with attendees on or before the day of the event via Brown Paper Tickets.

Cost
Free!

About the Speaker

Natalie McClure, PhD

Natalie McClure is a regulatory affairs consultant with extensive experience in drug development, regulatory affairs and quality assurance. She obtained a BS in Chemistry from the University of Michigan in 1974 followed by a PhD in Organic Chemistry from Stanford University in 1979. She started her career at Syntex Research, working in the process development laboratories on new synthetic approaches to prostaglandin and large-scale peptide synthesis and then changed career direction to drug regulatory affairs. Over the past 40 years, she has worked at several different companies, big and small, as an individual contributor and executive, and helped get over 6 drugs approved for marketing. She has filed more than 50 INDs (Investigational New Drugs), orphan drug applications and conducted many pre-IND meetings with the FDA. Natalie is an instructor at St Mary's University and the UC Berkeley Extension program offering several courses in drug development and regulatory affairs. Natalie is also very active in the American Chemical Society serving as chair and councilor of the Silicon Valley local section.

Abstract

Drug development requires a delicate balance between innovation, efficacy, safety, and regulatory compliance. This talk will explore the multifaceted process of bringing a new drug from the laboratory to the market, focusing on the critical role of regulatory affairs in ensuring patient safety and product quality. We will examine the key stages of drug development, including pre-clinical studies, clinical trials, and risk-benefit analysis. We will also discuss how to interpret the package insert. We will discuss how drug developers can work with the FDA to bring the new drug to the market.

Questions?

Please contact Elaine Yamaguchi at eyamaguchi08@gmail.com