

The Southern California Pharmaceutical Discussion Group (SCPDG) Announces our September 10, 2026, Meeting:

Pharmaceutical Product Development Strategy: A Holistic and Systematic Approach

Presented by
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Abstract: Many pharmaceutical companies face severe delays or costly setbacks during drug development, often incurring multi-million-dollar losses and losing years of critical time. These failure modes typically stem from key systemic and strategic gaps: the lack of comprehensive know-how planning, an ill-defined regulatory submission pathway, suboptimal submission data quality, disconnected workflows across development phases, inconsistent or poorly characterized active pharmaceutical ingredients (APIs), and a limited understanding of evolving regulatory requirements and agency expectations.

This presentation addresses these critical shortfalls through real-world case studies and actionable industry insights. The session will explore the core pillars of Chemistry, Manufacturing, and Controls (CMC), emphasizing strategic best practices across raw material qualification, analytical method development and validation, specification setting, cleaning validation, study quality management, extractables and leachables (E&L) evaluations, and regulatory inspection readiness. Additionally, the presentation will offer practical guidance on what studies to execute and how to implement them across different stages of drug development, striking an optimal balance between business priorities, technical rigor, and regulatory compliance.

Biography: Dr. Yan-Bo Yang is the President and CEO of BioPharmaDev, Inc. (www.biopharmadev.com), a Contract Research Organization (CRO) specializing in laboratory chemical testing, analytical services, and consulting services focused on product development strategy, quality, compliance, and FDA inspection readiness under both cGMP and non-cGMP environments for pharmaceutical, biotechnology, and medical device companies.

Prior to founding BioPharmaDev, Dr. Yang served as Director of Pharmaceutical Development at B. Braun Medical, Inc., overseeing all aspects of drug product development. Earlier in his career, he was the R&D Director at The Separations Group, Inc. (Vydac), leading the development and manufacturing of advanced HPLC packing materials and column technologies.

A recognized expert in separation science and drug development, Dr. Yang possesses deep and broad expertise across analytical chemistry, separation science, and pharmaceutical product development. His key contributions in chromatography encompass separation theory, stationary phase development, and applications for both small molecules and biologics. His comprehensive pharmaceutical development experience includes strategic planning, cGMP quality systems, raw material qualification, method development and validation, specifications setting, and extractables/leachables (E&L) studies.

Dr. Yang has also served as President and held senior leadership roles across various regulatory, policy-making, and professional organizations within the industry.

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Date: Thursday, September 10, 2026

Location: Waters Technologies District Office, 3540 Howard Way, Suite 100, Costa Mesa, CA 92626

Agenda: This is a hybrid event. On-Site check-in and Networking from 4:00-4:30PM PT. Zoom login will open at 4:15PM PT. Presentations and Discussion will be from 4:30-5:30PM PT. There is **no charge for on-site** or virtual attendance.

We would like to thank Waters for the use of their District office for the on-site meeting.

Registration: **Please register by 12:00 PM PDT, Tuesday, September 8,** using the link below or copy and paste into your browser: <https://www.eventbrite.com/e/scpdg-september-10-2026-meeting-tickets-1998785784086?aff=oddtcreator>

Important Notes: You must register to receive an emailed Zoom link for virtual attendance. You will receive the Zoom link after registration closes. If you need assistance logging in or during the presentation, please text me at 714 606 5907.

Social Media Links:

<https://www.linkedin.com/groups/6601347/>

Past Presentations and Calendar of Events are located on our web page at:

<https://www.aaps.org/aaps/membership-and-community/regional-discussion-groups/southern-california?CLK=c1e0e09f-9f30-4360-8fe2-1daebb1091fa>