SOCRA San Francisco Bay Area CHAPTER MEETING

Date: August 22nd, 2026

Time: 8:00 AM to 12:00 PM PST

Location: Virtual

Title / Topics: The 510(k) Pathway: Where We Stand and Where We Go Next

8:15 – 9:15 AM
Speaker
Kaushal Shah, Ph.D.
Director & Clinical Associate Professor
Clinical Research Management and Regulatory Science Programs
Arizona State University

Kaushal Shah, Ph.D. is Director and Clinical Associate Professor of Clinical Research Management and Regulatory Science Programs at Arizona State University, where she leads graduate education is focused on preparing professionals for evolving clinical research and regulatory environment. With a Ph.D. in Biochemistry and more than 20 years of experience across academia, industry, and consulting, she has worked with pharmaceuticals, biologics, medical devices, diagnostics, and emerging therapies in diverse global regulatory settings.

She also serves as President of the ACRP Phoenix Chapter, chairs the Embracing Change Conference for Clinical Research, and contributes to national and international initiatives advancing regulatory education. Drawing on both practical regulatory experience and academic leadership, Dr. Shah brings a pragmatic perspective to the 510(k) discussion, examining what the pathway has enabled, where questions remain, and how medical device regulation can continue to evolve.

Participants will:
The 510(k) pathway has played an important role in supporting medical-device innovation, allowing manufacturers to build on established technologies, introduce incremental improvements, and bring useful devices to patients more efficiently.

- Present a pragmatic picture of the 510(k) process, recognizing both its contribution to medical-device innovation and the concerns surrounding predicate-based clearance.
- Understand how regulation and governance work in practice, using examples from different industries to examine how regulatory approaches must reflect industry context, technological change, risk, and the consequences of regulatory failure.

- Chart a way forward for the 510(k) process by examining alternative approaches, safeguards, and regulatory options that could preserve innovation while strengthening confidence in device safety and performance.

Topic: From Clinic to Manuscript: Responsible AI Integration in Healthcare and Education

9:20 AM -10:20 AM

Speaker

Dr. Harichandra Vennelakanti
Physical Therapist and Software Systems Specialist
UT Southwestern Medical Center

Dr. Harichandra Vennelakanti is a licensed Physical Therapist and Software Systems Specialist at UT Southwestern Medical Center, working within Clinical Decision Support, Registries, and the Center for Informatics. He is currently a Master of Science in Health Informatics candidate at UT Southwestern's Peter O'Donnell Jr. School of Public Health. Combining his clinical expertise with technical innovation, Dr. Vennelakanti is the founder of V Health & Wellness, a virtual health platform delivering expert cancer rehabilitation and musculoskeletal care directly to patients wherever they are. A certified lymphedema and wound therapist, his research and peer-review contributions focus on oncology rehabilitation, clinical informatics, and the integration of artificial intelligence in physical therapy.

Objectives:

- List the primary ethical risks of using AI in patient care.
- Explain how algorithmic bias and "black box" systems can negatively impact clinical decisions.
- Describe the "human-in-the-loop" approach for keeping healthcare professionals in control of AI tools.
- Apply the current rules for using AI responsibly in medical research and academic writing.

Topic: Investigator Change: More Than a Name Change - Maintaining Oversight, Compliance, and Study Continuity

10:30 AM -11:30 AM

Speaker

Cynthia (Cindy) Dunn, MSN, RN, CCRA, CCRP, CHRC, CPC
Clinical Research & Compliance Consultant
Owner & Managing Director, Crescent City Research Consulting, LLC

Cynthia (Cindy) Dunn is a seasoned and diverse clinical research professional with 30 + years of healthcare experience including: clinical research, clinical research compliance, and oncology nursing. Having worked as an Oncology Research Coordinator, Interim Director Clinical and Regulatory Operations, Monitor, Project Manager and CRA Manager, Cindy offers valuable insight from both the site and sponsor perspectives of clinical research.

She collaborates with pharmaceutical companies on risk-based monitoring, site management, CRA oversight, CRO/vendor management, project management, auditing, TMF management, and inspection readiness.

Cindy holds a Master of Science in Nursing in Clinical Research Management from Duke University and maintains research certifications from ACRP, SOCRA, HCCA and AAPC. She is a contributing author to the *HCCA Research Compliance Professionals Handbook, 4th Edition* and lectures nationally and internationally on clinical research and compliance.

Objectives

1. Discuss common oversight and compliance gaps that may occur when an Investigator changes or leaves an organization.
2. Identify regulatory, sponsor, institutional, and operational requirements to consider during an Investigator change, including IRB review/approval, contracts, sponsor notification, Form FDA 1572, Delegation of Authority, training, systems, and more.
3. Review key processes for managing the Investigator transition, including continuity of oversight, participant safety, responsibility handoff, documentation, and final verification.

Networking

11:40 -12:30 PM

Build new connections with fellow professionals share ideas or grow your circle – come meet, chat and have fun!

Continuing Education (CE): SOCRA members may claim 4.0 CE credit per hour of education. SOCRA members will receive Certificates of Attendance at the completion of the event.

RSVP: NOTE: Remote site agreements are NOT required for this chapter meeting.

Details to enable virtual attendance will be sent to all attendees who have RSVP'd.

COST: FREE admission

Please register at

https://smccd.zoom.us/j/81181642599?pwd=Jdn4ztQAglAoPJrbsRrcjXIkuWZpuj.

registering, you will receive a confirmation email containing information about joining the meeting.

Questions: Please contact: socrabayareachapter@gmail.com

All SOCRA members and non-SOCRA members are welcomed
Please share this announcement with your colleagues.