The Southern California Pharmaceutical Discussion Group (SCPDG) Announces our November 20, 2025, Meeting:

Presentation 1 (15 Min)

Breaking the Bacterial Barrier: Enhanced Targeted Therapy on the Lipopolysaccharide of Pseudomonas aeruginosa Using a Phage-Antibiotic Cocktail

Presented by
Ms. Driti Rajkumar
Microbiology & Immunology Research Intern
Department of Microbiology and Immunology,
University of California, Irvine

Abstract: Antibiotic resistance has become a global crisis, demanding innovative solutions beyond traditional drugs. Phage therapy—using viruses that target specific bacteria—offers a promising alternative due to its precision, biofilm-degrading ability, and low toxicity. This study focused on *Pseudomonas aeruginosa*, a multidrug-resistant pathogen responsible for hospital and cystic fibrosis infections. We investigated the synergy between bacteriophage OCP-2 (isolated from North Ohio sewage) and aminoglycosides Gentamicin and Tobramycin. The phage-antibiotic combinations significantly inhibited bacterial growth in vitro. Sequence analysis of OCP-2 revealed tail proteins resembling depolymerases, supporting its capacity to break down polysaccharides. Both treatments targeted lipopolysaccharides to enhance bacterial eradication. Future work aims to re-engineer phages with multiple mechanisms of action to boost therapeutic potential. These results underscore phage-antibiotic synergy as a powerful strategy to combat antibiotic-resistant *P. aeruginosa*.

Biography: A passionate young scientist and advocate for mental wellness, Driti brings an inspiring blend of research, innovation, and leadership to every endeavor. As an R&D intern at AbbVie, Driti advanced data integrity in toxicology research and explored the microbiology behind *Clostridium botulinum* and Botox applications. At UC Irvine's Pearlman Lab, she conducted groundbreaking bacteriophage research uncovering new strategies to combat antibiotic resistance. A Johns Hopkins Global Health Leaders delegate, she studied public health challenges alongside global experts, deepening a commitment to equitable healthcare. Beyond the lab, Driti co-founded Gardening for Good, a student-led initiative promoting mental health, community, and sustainability. Driven by curiosity and compassion, she represents the next generation of innovators bridging science, health, and humanity.

Presentation 2 (45 Min)

Qualification of Primary Container Closures

Presented By
Aryo Nikopour
Vice President
Global Pharma Market Segment
Nelson Labs (A Sotera Health Company)

Abstract: Ensuring the integrity and performance of **primary container closure systems (CCS)** is a critical element of **pharmaceutical product quality, safety, and regulatory compliance**. As global regulatory expectations evolve — including requirements from the **FDA, EMA, USP <1207>, ISO 8871 series, and EP 3.2 guidelines** — manufacturers are under increasing pressure to implement robust qualification programs that address both **functional performance** and **chemical safety**.

This presentation highlights the **scientific and regulatory framework** for qualification of primary container closures, emphasizing the following key areas:

- **Extractables & Leachables (E&L) Studies**
- **Container Closure Integrity Testing (CCIT)**
- **Functional & Mechanical Qualification**
- **Regulatory Expectations & Industry Trends**

By combining **scientific rigor** with a **risk-based, patient-centric approach**, the presentation outlines best practices for developing a **comprehensive qualification strategy** that supports global submissions, mitigates compliance risk, and ensures that primary container closure systems perform reliably throughout a product's lifecycle.

Biography: Aryo Nikopour is an accomplished **Pharmaceutical Product Development Executive** with extensive experience in **CMC strategy, GMP manufacturing, and advanced analytical sciences**. His career spans leadership roles in both **innovator and CDMO/CRO environments**, with a strong record of bridging **scientific innovation, regulatory compliance, and business strategy**.

Mr. Nikopour has directed development programs across **small molecules, biologics, and combination products** — including **pre-filled syringes (PFS), auto-injectors, on-body injectors (OBIs), and wearable delivery systems**.

Companies & Key Roles

- **Solvay Pharmaceuticals** – Early career leadership in product development and manufacturing operations.
- **Alpharma** – Advanced roles in pharmaceutical development and analytical sciences.
- **PPD (Pharmaceutical Product Development, LLC)** – Led CMC and clinical development support for global clients.
- **Avrio Biopharmaceutical** – Senior leadership in biologics and sterile drug product manufacturing.
- **Nitto Avecia Pharma Services** – Directed CDMO operations and client strategy for complex drug development programs.
- **Nelson Labs (a Sotera Health Company)** – *Vice President, Global Pharma Market Segment* (Current Role). Provides executive leadership in **analytical testing, extractables & leachables, and regulatory-driven laboratory services**, supporting the global pharmaceutical and biopharmaceutical industries.

Date: Thursday, November 20, 2025
Location: Waters Technologies District Office, 3540 Howard Way, Suite 100, Costa Mesa, CA 92626
Agenda: This is a hybrid event. Check-in and Networking from 4:00-4:30 PM PT. Presentation and Discussion will be from 4:30-6:00 PM PT. Login will open at 4:20 PM PT.

Registration: Please register by Noon, Tuesday, November 18, using the link below or copy and type into your browser: https://www.eventbrite.com/e/main-presentation-qualification-of-primary-container-closures-tickets-1918062559749?aff=oddtdtcreator

Important Notes: You must register to receive an emailed Zoom link for virtual attendance. You will receive the Zoom link after registration closes at noon on Tuesday, November 18.

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