

**SoCal PDA Chapter Full Day Event Agenda – Aseptic Processing & Sterilization – Nov. 7, 2019\_V15\_190411**

<b>Start/End</b>	<b>Track 1</b>	<b>Track 2</b>
<b>7:30 - 9:00 AM</b>	<b>Women Leaders in Life Sciences</b> - Breakfast & Panel Discussion with Industry Moderator	
<b>8:00 - 9:30 AM</b>	<b>Registration + Networking + PDA Welcome and Opening Remarks</b>	
<b>9:30 - 10:15 AM</b>	<b>Keynote Speaker - Aseptic Processing Update on Industry and Regulatory Trends - The Path Forward</b> - Hal Baseman, Principal/COO, ValSource	
<b>10:15 - 11:00 AM</b>	<b>Understanding Aseptic Technique &amp; Cleanroom Behavior</b> -Paul Andrea, Principal Consultant, TAF Consulting, LLC	<b>New Developments in Lyophilization and Automatic Loading Systems</b> – Chris Fee, Technology and Business Development, IMA Life North America
<b>11:00 - 11:15 AM-Break</b>	<b>Networking Break / Student Poster Presentations</b>	
<b>11:15 – 11:45 AM</b>	<b>Innovations in Continuous Microbiological Environmental Monitoring</b> – Carol Julich, Sales Specialist, TSI	<b>Steam Sterilization “What we need to know to comply with EN285-A Case Study”</b> – Ron Mirian, SoCal Regional Manager, VTI Life Sciences
<b>11:45 - 12:30 PM</b>	<b>Media Fills/Aseptic Process Simulation and Validation</b> - Manjula Gosh, Director Quality, Allergan	<b>Isolators: Closing the Process for Advanced Therapy Medicinal Products (ATMPs)</b> -Les Edwards, VP, Technology and Business Development, SKAN
<b>12:30 - 1:30 PM-Lunch</b>	<b>Lunch and Vendor Announcements</b>	
<b>1:45 – 2:30 PM</b>	<b>Single-Use Technologies Used for Aseptic Processing and Final Filing Applications</b> - Jessica Frantz, Technology Expert – Aseptic Transfer Systems, Sartorius Stedim North America; Nancy Matti, Field Application Specialist, Sartorius Stedim Biotech	<b>Risk Based Approach to Cleaning and Disinfection</b> - Jim Polarine, Sr. Technical Services Manager, Steris
<b>2:30 - 3:15 PM</b>	<b>Innovations in Aseptic Processing - Opportunities &amp; Challenges for Implementation</b> , Chakradhar Padala, Director Process Development, Amgen	<b>Theory Behind Automatic Inspection Technologies for Visible Particle Detection &amp; Container Closure Integrity</b> , Edwin Martinez, Sr. Engineering Manager, Baxter
<b>3:15 - 3:30 PM-Break</b>	<b>Networking Break / Student Poster Presentations</b>	
<b>3:30 - 4:15 PM</b>	<b>Environmental Monitoring &amp; Aseptic Processing -Technology &amp; Microbiology</b> – Paul Hartigan, Global Product Line Manager for Software and Systems, PMS & Stacy Sutton, Vice President Quality Assurance, Argonaut Manufacturing Services	<b>Methods of Sterilization – Gamma, E-Beam, and X-Ray</b> , Betty Howard, Senior Radiation Sterilization Manager, Applied Sterilization Technologies, STERIS
<b>4:15 - 5:00 PM Case Studies</b>	<b>New Vial Filling Line Installation – End-to-End</b> , Norman Nicklaus, Principle Validation Engineer, Amgen & Eric Berg, Director of Quality, Amgen	<b>NextGen Now – The Future of Advanced Therapy Medicinal Products (ATMP) Facilities</b> - Peter Walters, Lead Process Engineer, CRB and Brita Salzmann, Process Engineer, CRB
<b>5:00 - 6:00 PM Network Reception</b>	<b>End-Of-Event Networking Reception + Student Poster Announcement Winner + Raffle + PDA Closing Remarks</b>	