

SoCal PDA Chapter Full Day Event Agenda – Aseptic Processing & Sterilization – Nov. 7, 2019_V12

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