SoCal PDA Chapter - 4th Annual Full Day Aseptic Processing & Sterilization Symposium - Nov. 7, 2019_7

Women Leaders in Life Sciences - Breakfast & Panel Discussion with Industry Moderator:

Moderator- Stacy Sutton, Vice President, Quality Assurance, Argonaut Manufacturing Services **Panelist**-

- -Regina Atim, PharmD, MBA, BCMAS-Human Factors Engineering Pharmacist-Becton Dickinson, Associate Clinical Professor-University of San Diego, Chair & Academic Alliance-HIMSS Southern California
- -Indah Kusumawardhani, Clinical & Regulatory Development Program Associate, Edwards Life Sciences
- -Liraz Oechsli, Director, Strategic Business Development, Microrite, Inc.
- -Vanessa Marquez, QC Manager, Microbiology, Sorrento Therapeutics
- -Cynthia Martinez, Ph. D., Dean of Students, Keck Graduate Institute

Full Day Event Con-Current Sessions & Speakers:

Keynote Speaker - Aseptic Processing Update on Industry and Regulatory Trends - The Path Forward Hal Baseman, Principal/COO, ValSource

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

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

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

Application of Single-Use Technologies in Final Filling Applications

Jessica Frantz, Sartorius Stedim North America Technology Expert – Aseptic Transfer Systems

Risk Based Approach to Cleaning and Disinfection

Jim Polarine, Sr. Technical Services Manager, Steris

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

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

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

Brita Salzmann, Process Engineer, CRB