**2019 PDA Practical Application of Sterile Manufacturing Workshop**

*Defining the Future with Novel Technology*

**March 13-14, 2019 | Marriott Marquis San Diego | San Diego, CA**

*As of March 1, 2019*

## Wednesday, March 13

3:15 p.m. - 6:00 p.m.
**Registration Open**

3:15 p.m. - 7:00 p.m.
**Exhibit Area Open**

4:15 p.m. - 6:00 p.m.
**P1: Novel Technologies Associated with Sterile Manufacturing**
**Moderator: Shelley Preslar,** General Manager, *Azzur Group South East*

Aseptic processing continues to be a hot topic in our industry. Consistently being able to produce a sterile product comes with a certain set of challenges and process requirements. Fortunately, the industry continues to push into the future, and novel techniques, equipment and technology are constantly evolving. In this session, we'll hear examples where novel technology has been utilized to improve aseptic production capabilities. What challenges did they face when implementing the new technology, and what did they learn when the project was over?

4:15 p.m. - 4:30 p.m.
**Welcome and Opening Remarks from the Planning Committee Co-Chair**
**Rebecca Brewer,** Vice President of Strategic Practices, *Quality Executive Partners*

4:30 p.m. - 5:00 p.m.
**Get Ready, Set, Transform! Looking into the Future of Sterile/Aseptic Manufacturing and its Transformation**
**Hal Baseman,** Chief Operating Officer, *ValSource LLC*
**Glenn Wright,** Senior Director, Quality Operations, *Exelead*

5:00 p.m. - 5:30 p.m.
**Aseptic Intervention Logging and Evaluation: A Case Study**
**Frederic B. Ayers,** Research Scientist, Indianapolis Parenteral Operations, *Eli Lilly and Company*

5:30 p.m. - 6:00 p.m.
**Questions and Answers/Discussion**

6:00 p.m. - 7:00 p.m.
**Networking Reception in Exhibit Area**

## Thursday, March 14

7:30 a.m. - 5:00 p.m.
**Registration Open**

7:30 a.m. - 8:30 a.m.
**Continental Breakfast**

8:30 a.m. - 10:00 a.m.
**P2: Rapid Microbiological Testing for Pharmaceutical Products**
**Moderator: Sabina Lancaster,** Global Sterility Assurance Manager, *Novartis Technical Operations*

The pharmaceutical industry has been slow to embrace rapid microbiological testing. Rapid testing can enable us to get product test results faster, allowing us to make the most appropriate decisions about our batches, saving valuable time and ensuring that product can reach the patient as quickly as possible while still assuring safety. With great technical advances being made in this area, the session will focus on using rapid methods in the lab including sterility test applications where several weeks are currently required to assess Biological Indicator growth. Learn from companies that are already using rapid methods and the challenges they have faced to validate and implement such solutions.

8:30 a.m. - 9:00 a.m.
**Implementation of Rapid Plate Count for Environmental Monitoring: A Case Study**
**Chris Knutsen, PhD,** Technical Fellow, Microbiology, *Bristol-Myers Squibb*

9:00 a.m. - 9:30 a.m.
**Sterility Testing Validation Using the BacT as an RMM: A Case Study**
**Ana P. Fonseca,** Principal Scientist, *Novartis*

9:30 a.m. - 10:00 a.m.
**Questions and Answers/ Discussion**

9:45 a.m. - 3:30 p.m.
**Exhibit Area Open**

10:00 a.m. - 10:30 a.m.
**Refreshment Break in Exhibit Area**

10:30 a.m. - 12:00 p.m.
**P3: Novel Technology for Training and Operations**
**Moderator: Rebecca Brewer,** Vice President of Strategic Practices, *Quality Executive Partners*

Reduction of human error non-conformance and the assurance of data integrity are present in everyone's minds today. Other industries have successful track records in the use of technology such as Virtual Reality, Augmented Reality, and novel computer interface devices that are hands free to reduce human errors through enhanced training and error-free operations, but these technologies are just beginning to make inroads to the pharmaceutical industry. Learn from case studies focusing on the selection, development, validation and implementation of a few of these novel technologies and how they have improved training, without having to enter the cleanroom, and operations, by reducing down-time and preventing human errors.

10:30 a.m. - 11:00 a.m.
**Using Virtual Reality to Transform Learning**
**Mirella Evans, BSc,** Head, Sterility Assurance Learning Center, *Novartis*

11:00 a.m. - 11:30 a.m.
**Design, Development and Validation Considerations for Advanced Training Technologies**
**Rebecca Brewer,** Vice President of Strategic Practices, *Quality Executive Partners*

11:30 a.m. - 12:00 p.m.
**Questions and Answers/Discussion**

12:00 p.m. - 1:30 p.m.
**Lunch**

1:30 p.m. - 3:00 p.m.
**P4: PUPSIT**
**Moderator: Dawn Downey, PhD,** Senior Consultant Engineer, *Eli Lilly and Company*

The regulatory requirement for Pre-Use Post Sterilization Integrity Testing (PUPSIT) stated in EU Annex 1 has caused companies filling sterile liquid products not only to include PUPSIT testing on new lines, but also to address legacy products where PUPSIT may not have been initially considered. The session will present discussions on current work by PDA and BPOG to consider the technical and compliance needs for PUPSIT as well as the impact on patient safety for sterile filtration systems. Case studies of implementation to address the requirement and the challenges involved will be reviewed. Learnings from companies that have already implemented PUPSIT and performed studies will include "lessons learned" in how the EU Annex 1 requirement was addressed.

1:30 p.m. - 2:00 p.m.
**A Case Study in PUPSIT Implementation**
**Steven Ensign,** Senior Consultant Engineer, *Eli Lilly and Company*

2:00 p.m. - 2:30 p.m.
**Update of the Workflows of the PUPSIT Task Force**
**Maik W. Jornitz**, CEO, *G-CON Manufacturing*

2:30 p.m. - 3:00 p.m.
**Questions & Answers/ Discussion Session Presenters and Additional Panelist**
**Hal Baseman,** Chief Operating Officer, *ValSource LLC*

3:00 p.m. - 3:30 p.m.
**Refreshment Break in Exhibit Area**

3:30 p.m. - 5:00 p.m.
**P5: Isolator Systems**
**Moderator: Richard Denk,** Head Containment, *SKAN AG*

The Isolator System Session will cover the new Draft Annex 1 requirements for aseptic processing within Isolators for Air supply, decontamination and glove management as well as cleaning and decontamination of indirect product contact surfaces. Furthermore, a case study is provided for the potential patient exposure to highly-potent API (HPAPI) from potential cross-contamination through the HPAPI Dispensing to the liquid filling and lyophilization process. The intent of this Session is to raise awareness of the risk(s) to patients and the implementation of adequate risk-based controls such as containment process(es), use of adequate surrogates in cleaning validation/verification, test method-sensitivity-based cleaning validation acceptance conditions as well as Operator Protection during manufacturing.

3:30 p.m. - 4:00 p.m.
**Requirements for Contamination and Cross Contamination Control**
**Richard Denk,** Head Containment, *SKAN AG*

4:00 p.m. - 4:30 p.m.
**Design of a HPAPI Production Suite from Dispensing to Liquid Filling and Lyophilization Processes**
**Amir Zandnia,** Senior Project Engineer, *Fresenius Kabi*

4:30 p.m. - 5:00 p.m.
**Questions and Answers/ Discussion with Session Presenters and Additional Panelists**
**Hal Baseman,** Chief Operating Officer, *ValSource, LLC*
**Shelley Preslar,** General Manager, *Azzur Group South East*

5:00 p.m.
**Closing Remarks & Adjournment from the Program Planning Committee Co-Chair**
**Dawn Downey, PhD,** Senior Consultant Engineer, *Eli Lilly and Company*