



2018 PDA Sterile Medicinal Products Manufacturing Conference
Addressing thought Provoking Topics for Sterile Manufacturing Process Reliability
May 14-15, 2018 | Hyatt Regency Bethesda Hotel | Bethesda, MD
As of May 7, 2018

Monday, May 14

7:00 a.m. – 5:30 p.m.

Registration Open

7:15 a.m. – 8:15 a.m.

Continental Breakfast

8:15 a.m. – 8:30 a.m.

Welcome and Opening Remarks from Conference Co-Chair

Gabriele Gori, Vice President, Audit and Risk Management, Global Quality, *GSK Vaccines*

8:30 a.m. – 10:00 a.m.

P1: Opening Plenary: The State of Sterile Product Manufacturing: Challenges and Opportunities for Improvement

Moderator: Gabriele Gori, Vice President, Audit and Risk Management, Global Quality, *GSK Vaccines*

Session Description: The conference takes the opportunity of the on-going changes in the European regulations for sterile medicinal product manufacturing to discuss how to move forward to true risk-based manufacturing and control, in order to enhance process robustness and sterility assurance, thus ensuring supply reliability. The necessity for moving forward is illustrated by changes of the scenario where we operate, such as the availability of modern technologies, the development of innovative personalized and alternative therapies, the globalization of the manufacturing and supply chain as well as by increased regulatory expectations. What needs to change is our understanding of the limitations of traditional methods for process and contamination control, our hesitancy to use new technologies, and our awareness of the need to develop manufacturing methods to meet new therapies. This session will present a general overview on positions from industry and health authority on the above topics and will solicit an active dialogue with the participants that will continue through the subsequent conference tracks.

8:30 a.m. – 8:55 a.m.

An Industry Perspective on the Challenges of Modern Sterile Product Manufacturing and the Opportunities for Change

James Klein, PhD, Associate Vice President, Global Technical Operations S&V COE, Sterile Manufacturing Technical Operations, *Merck & Co., Inc.*

8:55 a.m. – 9:20 a.m.

Sterile Product Manufacturing: Are the Regulators Moving Forward

Marla Stevens-Riley, PhD, Master Microbiology Reviewer, Quality Assessment Lead, CDER, OPQ, *FDA*

9:20 a.m. – 9:45 a.m.

Sterile Medicines: An Inspectors Perspective

Andrew Hopkins, Expert GDMP Inspector, *Medicines and Healthcare Products Regulatory Agency*

9:45 a.m. – 10:00 a.m.

Questions and Answers/Discussion

9:45 a.m. – 6:30 p.m.

Exhibit Area Open

10:00 a.m. – 10:45 a.m.

Refreshment Break in Exhibit Area

10:45 a.m. – 12:15 p.m.

P2: Quality Systems: What Works, What can be Improved, What Should Change?

Moderator: Andrew Hopkins, Expert GDMP Inspector, *Medicines and Healthcare Products Regulatory Agency*

Session Description: Whilst there is common agreement that the implementation of Quality Risk Management (QRM) principles is critical for an efficient and effective design and implementation of facilities and processes in a modern pharmaceutical company, there are instances where the implementation of these principles does not always translate into proper practices in the actual manufacturing and control activities that reduce residual risk to patient to an acceptable level. The purpose of this session is to

provide clarity on those principles and provide a real case study on their effective implementation, for a better understanding on such a powerful approach and the associated benefits.

10:45 a.m. – 11:15 a.m.

Overall Theory of Quality Risk Management

Ghada Haddad, MBA, Executive Director, Global cGMP & Compliance Auditing Organization, *Merck & Co., Inc.*

11:15 a.m. – 11:45 a.m.

Case Study on Quality Risk Management

Mitchell B. Garber, Director, Clinical Global Supplies Sterile, *GlaxoSmithKline*

11:45 a.m. – 12:15 p.m.

Questions and Answers/Discussion

12:15 p.m. – 1:45 p.m.

Lunch on Your Own. Exhibit Area Closed. A listing of local restaurants is available at the PDA registration desk.

1:45 p.m. – 3:15 p.m.

P3: Personnel and Air Monitoring: How to Control the Most Important Variables

Moderator: Frederic B. Ayers, Consultant Scientist, *Eli Lilly and Company*

Session Description: This plenary session will focus on one of the most reviewed metrics for evaluating a facilities overall environmental control. Monitoring of the environment is a required activity that must be reviewed at frequencies that are relevant to the processes within the facilities being monitored. Join us as Personnel Qualification and Use of Settle Plates are discussed in depth.

1:45 p.m. – 2:15 p.m.

Personnel Qualification for Aseptic Processing

David Hussong, PhD, Chief Technical Officer, *Eagle Analytical Services* and Chair of the USP Microbiology Committee

2:15 p.m. – 2:45 p.m.

Viable Air Monitoring for Aseptic Processing: Active Versus Passive Air Options

Marsha Steed (Hardiman), Senior Consultant, *ValSource LLC*

2:45 p.m. – 3:15 p.m.

Questions and Answers/Discussion

3:15 p.m. – 4:00 p.m.

Refreshment Break in Exhibit Area

4:00 p.m. – 5:30 p.m.

P4: Science- and Risk-Based Decision-Making to Drive Best Practice in Sterile Product Manufacturing

Moderator: Hal Baseman, Chief Operations Officer, *ValSource LLC*

Session Description: Once sterility has been achieved for a process or product, maintenance of integrity is paramount in the manufacture of sterile products. With aseptic processing, sterile integrity of the aseptic line and process must be maintained after sterilization-in-place until the manufacturing campaign is completed. For sterile pharmaceutical products, sterile integrity must be maintained throughout the product's shelf-life. This session will highlight the risk-based considerations around sterile filtration including pre-use post-sterilization integrity testing. Additionally, recommended best demonstrated scientific practice for container closure integrity testing will be summarized based on current content of the ongoing revision of PDA Technical Report No. 27 on Pharmaceutical Packaging.

4:00 p.m. – 4:10 p.m.

Update on the PDA/BPOG PUPSIT Task Force

Hal Baseman, Chief Operations Officer, *ValSource LLC*

4:10 p.m. – 4:40 p.m.

Application of Risk-Based Approaches for Sterilizing Filtration

Brian Joseph, Senior Scientist, Regulatory and Validation Consultancy, *Pall Life Sciences*

4:40 p.m. – 5:10 p.m.

Considerations for a Science- and Risk-Based Container Closure Integrity Testing Program

Sangeetha R. Nair, Senior Quality Technical Consultant, *Baxter Healthcare Corporation*

5:10 p.m. – 5:30 p.m.

Questions and Answers/Discussion

5:30 p.m. – 6:45 p.m.

Networking Reception

Tuesday, May 15

7:15 a.m. – 3:45 p.m.

Registration Open

7:15 a.m. – 8:15 a.m.

Continental Breakfast

7:15 a.m. – 8:00 a.m.

Breakfast Session: Annex 1 PDA Commenting Committee Report

Moderator: Hal Baseman, Chief Operations Officer, *ValSource LLC*

Session Description: PDA assembled a team of sterile manufacturing and quality control experts. Using input from PDA members, documented PDA positions from its Technical Reports, Aseptic Processing Points to Consider (2015, 2016), Journal Articles, and the team's acquired knowledge, this team reviewed the Annex 1 Revision, and where necessary, offered comments and recommendations on and to the Annex 1 revision. Those comments have been submitted to the European Commission for consideration. This session will review the PDA commenting process, key comments submitted by PDA, the rationale for PDA proposed changes, and answer questions related to draft Annex 1 revision and PDA response.

7:15 a.m. – 8:00 a.m.

Gabriele Gori, Vice President, Audit and Risk Management, Global Quality, *GSK Vaccines*

8:15 a.m. – 9:45 a.m.

P5: Aseptic Process Monitoring: How can we Align Modern Requirements and Technologies with Traditional Methods and Expectations

Moderator: Frederic B. Ayers, Consultant Scientist, *Eli Lilly and Company*

Session Description: This plenary session will focus on other metrics for evaluating the overall aseptic process control for manufacturing facilities. Aseptic process simulations and airflow visualization are critical activities for process and facility evaluations. Join us for these in-depth conversations on aseptic process simulations and airflow visualizations.

8:15 a.m. – 8:45 a.m.

Recovery of Propionibacterium Acnes from an Aerobic Process and Implication to the Process Simulation Program

Kenneth W. Boone, Associate Director, Sterile & Microbiology Quality Assurance, *Merck & Co., Inc.*

8:45 a.m. – 9:15 a.m.

Visualization of Airflow Patterns: From Software Simulation to Aseptic Behavior Optimization

Geert Vandenbossche, PhD, Global Head NTO Quality Strategic Initiatives, *Novartis*

9:15 a.m. – 9:45 a.m.

Questions and Answers/Discussion

9:30 a.m. – 3:45 p.m.

Exhibit Area Open

9:45 a.m. – 10:30 a.m.

Refreshment Break in Exhibit Area

10:30 a.m. – 12:00 p.m.

P6: Concepts and Misconceptions for Terminal Sterilization with Moist Heat and Rendering Isolators Sterile

Moderator: Geert Vandenbossche, PhD, Global Head NTO Quality Strategic Initiatives, *Novartis*

Session Description: Terminal sterilization of non-porous loads has different requirements and critical process parameters than porous loads. The presentation will highlight the key differences and bring clarity to points that are not addressed in the Annex-1 draft. The pharmaceutical industry has been moving away from conventional Grade A filling lines with B background to Isolator technology in grade D background. As a result, there is a need for line setup and format changes to take place with an open isolator in a grade D environment. A key question today is how to render all critical surfaces sterile, taking into account the following; a. limitation for VHP and other surface decontamination techniques to contact any hidden surfaces and b. the challenges faced to enter large format parts e.g. vibratory bowls and rails. The goal is to design a process that results in the highest possible sterility assurance level.

10:30 a.m. – 11:00 a.m.

Moist Heat Sterilization Misconceptions

Roy McLean, Senior Manager, Operations Support, R&D Sterility Assurance, *Baxter Healthcare Corporation*

11:00 a.m. – 11:30 a.m.

Sterility Assurance for Equipment in Isolators: Challenges and Possibilities

Henrietta Vinnerås, Senior Manager Microbiology and Aseptic Technique, *Fresenius Kabi*

11:30 a.m. – 12:00 p.m.

Questions and Answers/Discussion

12:00 p.m. – 1:30 p.m.

Lunch on Your Own. Exhibit Area Closed. A listing of local restaurants is available at the PDA registration desk.

1:30 p.m. – 3:00 p.m.

P7: Aseptic Processing: Where Can We Go From Here?

Moderator: Gabriele Gori, Vice President, Audit and Risk Management, Global Quality, *GSK Vaccines*

Session Description: Increased knowledge on aseptic manufacturing and improved process design can open the door to enhanced control strategies which are more efficient and effective than the ones implemented today. The introduction of new therapies are changing risk profiles, typical contributors of contamination, and forcing the industry to look for innovative approaches for process control and product release. This session will explore real time release for aseptic processing and other regulatory and process challenges raised by new products, such as those from cell and gene therapy.

1:30 p.m. – 2:00 p.m.

The Future of Aseptic Processing: Parametric Aseptic Release

Frederic B. Ayers, Consultant Scientist, *Eli Lilly and Company*

2:00 p.m. – 2:30 p.m.

Aseptic Processing Controls and Simulation Design for Cell Therapies

Terrence J. Rindler, Associate Director, Validation, *Juno Therapeutics*

2:30 p.m. – 3:00 p.m.

Questions and Answers/Discussion

3:00 p.m. – 3:45 p.m.

Refreshment Break in Exhibit Area

3:45 p.m. – 4:30 p.m.

P8: Panel Discussion: A Wrap Up of the Conference with Key Speakers, Experts, and Regulators

Moderator: Hal Baseman, Chief Operations Officer, *ValSource LLC*

Session Description: The objective of this conference is to promote dialogue, deliver knowledge, and to leave attendees, participants, and speakers with a better understanding of the challenges, opportunities, and answers the sterile medicinal products manufacturing industry is and will be facing. Key speakers, experts, and regulators will take places at the podium to present final thoughts on conference proceedings and field questions from the audience. This is the attendees' last opportunity to present their views and clarify presenter's positions on topics presented or any topic related to the conference.

Gabriele Gori, Vice President, Audit and Risk Management, Global Quality, *GSK Vaccines*

Andrew Hopkins, Expert GDMP Inspector, *Medicines and Healthcare Products Regulatory Agency*

Richard Johnson, President and CEO, *PDA*

James Klein, PhD, Associate Vice President, Global Technical Operations S&V CO, Sterile Manufacturing Technical Operations, *Merck & Co., Inc.*

Marla Stevens-Riley, PhD, Master Microbiology Reviewer, Quality Assessment Lead, CDER, OPQ, *FDA*

4:30 p.m. – 5:00 p.m.

Closing Remarks from Conference Co-Chair

Hal Baseman, Chief Operations Officer, *ValSource LLC*