2017 PDA Annex 1 Workshop

October 2-3, 2017 | Omni Shoreham Hotel | Washington, DC

Monday, October 2

7:00 a.m. – 5:30 p.m. | Palladian Foyer
Registration Open

7:00 a.m. – 8:30 a.m. | Palladian Foyer
Continental Breakfast

8:15 a.m. – 8:30 a.m. | Diplomat Ballroom
Welcome and Opening Remarks from Workshop Co-Chair
Hal Baseman, Chief Operating Officer, *ValSource, LLC*

8:30 a.m. – 10:00 a.m. | Diplomat Ballroom
P1: Opening Plenary: Overview and Revision Process of Annex 1
Moderator: Richard M. Johnson, President and CEO, *PDA*

Session Description: This opening plenary will present the needs, background, procedure, and content of the revised Annex 1 GMP guidance for sterile pharmaceutical product manufacturing from the perspective of the leadership of the Health Authority committee responsible for the preparation of the revision, as well as from the perspective of the industry Chair of the task force that authored the recently published *PDA Aseptic Processing Points to Consider Parts 1 and 2*.

8:30 a.m. – 9:00 a.m.
Annex 1 Overview: Updates and Revisions
Overview of existing content with modern aseptic processing challenges and process of revising. What to expect.
Andrew Hopkins, Expert GMDP Inspector, *Medicines and Healthcare Products Regulatory Agency (MHRA)*

9:00 a.m. – 9:30 a.m.
Industry Perspectives: Challenges and Opportunities
Challenges to aseptic processing and how guidance (revised Annex 1) may help industry with meeting challenges. Meeting expectations.
Hal Baseman, Chief Operating Officer, *ValSource, LLC*

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

9:45 a.m. – 6:30 p.m. | Bird Cage Walk
Exhibit Area Open

10:00 a.m. – 10:45 a.m. | Bird Cage Walk
Refreshment Break in Exhibit Area

Monday, October 2, continued

10:45 a.m. – 12:15 p.m. | Diplomat Ballroom
P2: Risk-Based Thinking and Cleanroom Design
Moderator: Guenther Gapp, PhD, Consultant, *Gapp Quality GmbH*

Session Description: Regulators and Industry experts agree that modern risk- and science-based approaches should be used to develop and implement control strategies and acceptance criteria designed to ensure the establishment and maintenance of suitable manufacturing conditions that affect the quality and safety of products. This session will provide concrete examples on how risk management tools and approaches can be used in practice to not only to identify risk, but also to allow the improvement of processes, facilities, and control strategies.

10:45 a.m. – 11:15 a.m.
How Risk Tolerance Impacts our Thinking about Aseptic Processes
What Scares Us About Risk? How can we make it work for us?
James Vesper, PhD, Director, Learning Solutions, *ValSource, LLC*

11:15 a.m. – 11:45 a.m.
Cleanroom Design
The use of design as a primary means to mitigate contamination risk.
Phil DeSantis, MS, Principal, *DeSantis Consulting Associates*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. – 1:30 p.m. | Palladian Foyer
Networking Luncheon

1:30 p.m. – 3:15 p.m. | Diplomat Ballroom
P3: Personnel and Environmental Monitoring
Moderator: William H. Miele, PhD, Director, Global Aseptic Support, *Pfizer Inc.*

Session Description: Personnel and environmental monitoring are key assessment and control processes to minimize risk in aseptic processing. Some regulatory requirements are stated quantitatively while others may describe expectations with little information addressing "how to". This leaves a manufacturing site to incorporate established regulation into the development and description of their own process, possibly resulting in varying approaches and programs in our industry. This session will explore current industry approaches in the context of an evolving environment dealing with the science, technology, and conventions of today.

1:30 p.m. – 2:00 p.m.
Personnel
The qualification, supervision, and monitoring of our most essential aseptic processing factor.
Guenther Gapp, PhD, Consultant, *Gapp Quality GmbH*

2:00 p.m. – 2:30 p.m.
Environmental Monitoring
Learning how to effectively look, see, and interpret what we see.
Edward Tidswell, PhD, Executive Director, Sterile Quality Assurance, *Merck & Company*

2:30 p.m. – 3:15 p.m.
Questions and Answers/Discussion

3:15 p.m. – 4:00 p.m. | Bird Cage Walk
Refreshment Break in Exhibit Area

Monday, October 2, continued

4:00 p.m. – 5:30 p.m. | Diplomat Ballroom
P4: Breakout Session 1 | *What will work and what can be better?*
Moderator: Hal Baseman, Chief Operating Officer, *ValSource, LLC*

Session Description: Workshop attendees will break into smaller, facilitated groups based on a colored dot on each attendee's badge. This session offers the opportunity to discuss a series of topics and questions related to the revised Annex 1 content. Comments on specific items and topics will be noted for later discussion and critique. Emphasis will be given to topics and requirements which present manufacturing and inspection challenges and ways to meet those challenges. At the end of the session, each group will have the opportunity to give feedback on a particular topic.

4:00 p.m. – 5:00 p.m.
Breakout Group Discussions

5:00 p.m. – 5:30 p.m.
Group Discussion Feedback

5:30 p.m. – 6:30 p.m. | Empire Terrace
Networking Reception

Tuesday, October 3

7:00 a.m. – 4:30 p.m. | Palladian Foyer
Registration Open

7:00 a.m. – 8:30 a.m. | Palladian Foyer
Continental Breakfast

8:30 a.m. – 10:00 a.m. | Diplomat Ballroom
P5: Industry and Regulatory Challenge Topic Debate
Moderator: Hal Baseman, Chief Operating Officer, *ValSource, LLC*

Session Description: Day 2 sessions are designed to encourage and stimulate the exchange of views on topics where industry consensus may not be yet fully formed. The sessions will be organized into point-counterpoint interactive discussions with experts presenting alternate views, advantages, and potential disadvantage of selected topics. The sessions will begin with a report on two important, recently published PDA surveys – addressing Aseptic Processing in general and PUPSIT (post sterilization, pre-use, and integrity test). Following the survey report, the first point-counterpoint discussion will involve the relative benefits and risks of the use of PUPSIT in sterile product manufacturing.

8:30 a.m. – 9:00 a.m.
PDA Survey Analysis (Aseptic and PUPSIT Surveys)
What are your colleagues doing and how do you compare?
Richard M. Johnson, President and CEO, *PDA*

9:00 a.m. – 10:00 a.m.
Pre-Use Post Sterilization Integrity Testing (PUPSIT): Benefits versus Risk
PUPSIT as mitigation of process contamination risk.
Andrew Hopkins, Expert GMDP Inspector, *Medicines and Healthcare Products Regulatory Agency (MHRA)*

Is PUPSIT worth the potential added risk?
Maik W. Jornitz, MS, CEO, *G-CON Manufacturing, Inc.*

9:45 a.m. – 4:15 p.m. | Bird Cage Walk
Exhibit Area Open

10:00 a.m. – 10:45 a.m. | Bird Cage Walk
Refreshment Break in Exhibit Area

Tuesday, October 3, continued

10:45 a.m. – 12:45 p.m. | Diplomat Ballroom
P6: Vaporized Hydrogen Peroxide (VHP), Container Closure Integrity Testing, and Excursions in Grade-A Environment
Moderator: Steven J. Lynn, MS, CMQ/OE Global Head, Group Compliance and Audit, *Novartis Services, Inc.*

Session Description: The revised Annex 1 is expected to contain changes to how companies deal with multiple facets of aseptic manufacturing. Join us as we discuss a few of these key topics, including new technologies and usability in container closure integrity testing (CCIT), vaporized hydrogen peroxide (VHP) decontamination, and excursions in a Grade-A environment.

10:45 a.m. – 11:15 a.m.
Design of a Meaningful Control Strategy for CCI
Should CCI be used as an in-process release criterion?
Derek Duncan, PhD, Director, Product Line Europe, *LIGHTHOUSE Instruments*

11:15 a.m. – 11:45 a.m.
Decision Tree on the Use of VHP
Is VHP an effective means to decontaminate or sterilize indirect product contact parts?
Geert Vandenbossche, PhD, Global Head Biologics Technical Development and Manufacturing Quality - Drug, *Novartis*

11:45 a.m. – 12:15 p.m.
Excursions in Grade-A Environment
Should microbiological excursions in the Grade-A Environment result in batch rejection?
Marcia C. Baroni, Director, QC Microbiology & EM/Sterility Assurance, *Eli Lilly and Company*

12:15 p.m. – 12:45 p.m.
Questions and Answers/Discussion

12:45 p.m. – 2:00 p.m. | Palladian Foyer
Networking Luncheon

2:00 p.m. – 3:30 p.m. | Diplomat Ballroom
P7: Breakout Session 2 | *Where do we go from here?*
Moderator: Hal Baseman, Chief Operating Officer, *ValSource, LLC*

Session Description: Attendees will break out into groups to debate some of the key issues related to the previous sessions. This session will include several specific questions for discussion, and members of the Program Planning Committee will facilitate the discussion to try to develop consensus. At the end of the session, each group will have the opportunity to give feedback on a discussion topic.

2:00 p.m. – 3:00 p.m.
Breakout Group Discussions

3:00 p.m. – 3:30 p.m.
Group Discussion Feedback

3:30 p.m. – 4:15 p.m. | Bird Cage Walk
Refreshment Break in Exhibit Area

4:15 p.m. – 5:00 p.m. | Diplomat Ballroom
P8: Closing Plenary: Panel Discussion on the Draft Revision of Annex 1 and the Points of Agreement/Controversy
Moderator: Richard M. Johnson, President and CEO, *PDA*

Session Description: The final session features a panel of industry and regulatory experts that will participate in an interactive panel discussion regarding key topics on the Annex 1 draft revision.

Panelists
Hal Baseman, Chief Operating Officer, *ValSource, LLC*
Andrew Hopkins, Expert GMDP Inspector, *Medicines and Healthcare Products Regulatory Agency (MHRA)*
William H. Miele, PhD, Director, Global Aseptic Support, *Pfizer Inc.*

5:00 p.m. | Diplomat Ballroom
Closing Remarks from PDA Leadership
Richard M. Johnson, President and CEO, *PDA*