The Parenteral Drug Association presents the...

2017 PDA Annex 1 Workshop

October 2-3, 2017 | Washington, DC

Omni Shoreham Hotel

Exhibition: October 2-3

#2017Annex1

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The Annex 1 Revision: A Unique Opportunity to Better Understand and Influence the Guidance

pda.org/2017Annex1

This preliminary agenda is current as of July 20, 2017

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS

PROGRAM PLANNING COMMITTEE

Program Co-Chairs:

Hal Baseman
ValSource, LLC

Gabriele Gori
GSK Vaccines

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DeSantis Consulting Associates

Guenther Gapp, PhD
Gapp Quality GmbH

Steven J. Lynn, MS, CMQ/OE
Novartis Services, Inc.

William H. Miele, PhD
Pfizer, Inc.

Vincent O'Shaughnessy
Amgen, Inc.

Edward Tidswell, PhD
Merck & Co./Merck Sharp & Dohme

Jason E. Brown
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Crystal Roberson
PDA

A MESSAGE FROM THE PROGRAM CO-CHAIRS

Hal Baseman
ValSource, LLC

Gabriele Gori
GSK Vaccines

Dear Friends and Colleagues,

We welcome your participation in this special PDA Workshop and symposium addressing the most timely and important global sterile product manufacturing topic today: understanding and implementing the revisions to EU Annex 1, *Manufacture of Sterile Medicinal Products of the European Union Guidelines to Good Manufacturing Practice of Medicinal Products for Human and Veterinary Use.*

The *2017 PDA Annex 1 Workshop* is designed to present the newly released draft revision to Annex 1, developed by a joint working group between PIC/S and EMA with input from global health authorities; it will be broadly implemented inside and outside of the European Union. The Workshop will bring together regulators, contributors, industry experts, and the actual personnel who must implement the new requirements, with the purpose of reviewing the content of the revised Annex, focusing on the most critical changes and regulatory expectations and their impact on the daily operations of global manufacturers of sterile products. This will be a unique and time-sensitive opportunity to hear explanation of the revision from experts, understand underlying principles, background, interpretation and expectations, and provide direct input to health authority representatives on content and usage of the Annex.

The Workshop will start with an explanation of the Annex revision process and content delivered by Andrew Hopkins, Committee Chair of the PIC/S EMA Working Group for the revision of Annex 1. Presentations will focus on PDA and industry perspectives on the need for and impact of change, risk-based thinking and revision content, and critical aspects of sterile manufacturing, including clean room design/operation, personnel training and performance, and effective environmental monitoring.

Day two will begin with a presentation on the results of two recently published PDA Surveys: the *2017 PDA Aseptic Processing Survey* and the *PUPSIT* (Pre-Use, Post-Sterilization Integrity Test) *Survey*. Discussion will then turn to the more debated topics that may especially affect your aseptic processing operations, exploring areas for which there is not yet consensus and those in need of further explanation. Experts will address advantages and disadvantages as well as risks and benefits of four key topics: Pre-Use, Post-Sterilization, Pre-Use and Integrity Test of sterilizing filters; Vapor Phase Hydrogen Peroxide (VHP) treatment of indirect product contact surfaces; Container Closure Integrity (CCI) testing as a batch release criteria; and response to microbiological excursions in the critical Grade A environments.

Both days will include small-group breakout discussions to enable all attendees to provide their comments. The closing session will be an interactive panel discussion further addressing topics discussed during the Workshop, reports from the breakout sessions, and a summary of input to be provided to health authorities on the revision.

If you are involved in the planning, decision making, and risk management of manufacturing, quality, validation, technical support, and regulatory affairs for aseptically processed sterile pharmaceutical products, this is an essential meeting for you! Join us to gain a more complete understanding of changing global regulatory expectations with regard to sterile product manufacturing and to share your opinions on these expectations.

We look forward to your participation and input!

GENERAL INFORMATION, REGISTRATION

FOUR WAYS TO REGISTER

1. Click	**pda.org/2017Annex1**
2. Fax	+1 (301) 986-1093
3. Mail	PDA Global Headquarters Bethesda Towers 4350 East West Highway, Suite 600 Bethesda, MD 20814 USA
4. Phone	(301) 656-5900 ext. 115

VENUE

Omni Shoreham Hotel
2500 Calvert St., NW
Washington, DC 20008 USA
Phone: +1 (202) 234-0700
Website: www.omnihotels.com/hotels/washington-dc-shoreham
Rate: Single: $259, plus applicable state and local taxes.
Cut-Off Date: September 4, 2017 (Rooms must be secured by this date in order to receive the PDA rate). Rates are guaranteed until the PDA block of rooms are sold out on a first come basis.

CONTINUING EDUCATION CREDITS

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

ALERT: ACPE and the National Association of Boards of Pharmacy developed the Continuing Pharmacy Education (CPE) Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

2017 PDA Annex 1 Workshop
CPE: ACPE # 0116-0000-17-019-L04-P | 1.2 CEUs
Type of Activity: *Knowledge*

LEARNING OBJECTIVES

Upon completion of this Workshop, you will be able to:

- Explain the contents, health authority expectations and rationale of the draft revision to EU Annex 1, including many of the more complex manufacturing process control strategies
- Discuss aseptically manufacturing healthcare sterile products in a modern, global, technological and regulatory environment
- Interpret the latest regulatory expectations and industry standards for aseptic processing and clean room operation
- Explain the use of risk- and science-based approaches to aseptic process design, validation, testing, monitoring and decision making
- Identify best practices for clean room personnel, material decontamination and work flows in the aseptic environment
- Summarize the challenges faced by peers in the aseptic process industry

WHO SHOULD ATTEND:

Job Function: Microbiology | Validation | Engineering | Quality | Regulatory | Sterility Assurance | Sterile Operations | Product and Process Development | Operations and Quality | GMP Consultants | GMP Service Providers

Department: Manufacturing | Formulation | Compliance | Engineering | QA/QC | Process Design | Regulatory Affairs | Research and Development | Technical Operations | Validation

Level of Expertise: Senior Management | Senior Scientists | Project/Program Leader | Technical Contributor | Supervision and Shop Floor Management | Trainers | Aseptic Processing Subject Matter Experts | Senior Management | Senior Professionals

WORKSHOP REGISTRATION HOURS

Monday, October 2: 7:00 a.m. – 5:30 p.m.
Tuesday, October 3: 7:00 a.m. – 4:15 p.m.

DRESS/ATTIRE

Business casual attire is recommended for the *2017 PDA Annex 1 Workshop*. Since the temperature in meeting rooms tends to be cool, please bring a jacket or sweater for your comfort.

SPECIAL REQUIREMENTS

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration@pda.org.

CONTACT INFORMATION

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MONDAY, OCTOBER 2 AGENDA

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

7:00 a.m. – 8:30 a.m.
Continental Breakfast

8:15 a.m. – 8:30 a.m.
Welcome and Opening Remarks from Program Planning Committee Co-Chair
Hal Baseman, Chief Operating Officer, *ValSource, LLC*

8:30 a.m. – 10:00 a.m.
P1: Overview and Revision Process of Annex 1
Moderator: Hal Baseman, Chief Operating Officer, *ValSource, LLC*

Session Description: This Workshop will kick off with a session presenting the needs, background, procedure, and content of the revised Annex 1 GMP guidance for sterile pharmaceutical product manufacturing. This session will be presented from the perspective of the leadership of the Health Authority Committee responsible for the preparation of the revision and from the perspective of the industry Chair of the task force that authored the recently published PDA *Points to Consider for Aseptic Processing: Parts 1 and 2.*

8:30 a.m. – 9:00 a.m.
Annex 1 Overview: Updates and Revisions
Andrew Hopkins, GMP Inspector, *Medicines and Healthcare Products Regulatory Agency (MHRA),* and Committee Chair of the PIC/S EMA Working Group for the Revision of Annex 1

9:00 a.m. – 9:30 a.m.
Industry Perspectives: Challenges and Opportunities
Gabriele Gori, Head of Global Audit and Risk Management, Quality Vaccines, *GSK Vaccines*

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

9:45 a.m. – 7:00 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: Risk-Based Thinking and Clean Room Design
Moderator: Gabriele Gori, Head of Global Audit and Risk Management, Quality Vaccines, *GSK Vaccines*

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, the goal of which is to ensure the establishment and maintenance of suitable manufacturing conditions that affect the quality and safety of products. This session will provide concrete examples of how risk-management tools and approaches can be used in practice 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.
Use of Risk-Based Thinking in Aseptic Process Design and Evaluation
Hal Baseman, Chief Operating Officer, *ValSource, LLC*

11:15 a.m. – 11:45 a.m.
Clean Room Design
Phil DeSantis, MS, Principal, *DeSantis Consulting Associates*

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

MONDAY, OCTOBER 2 (CONTINUED)

12:15 p.m. – 1:30 p.m.
Networking Luncheon

1:30 p.m. – 3:15 p.m.
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 its 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
Guenther Gapp, PhD, Consultant, *Gapp Quality GmbH*

2:00 p.m. – 2:30 p.m.
Environmental Monitoring
Edward Tidswell, PhD, Executive Director, Sterile Quality Assurance, *Merck & Co./Merck Sharp & Dohme*

2:30 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: Breakout Session 1
Moderator: Hal Baseman, Chief Operating Officer, *ValSource, LLC*

Session Description: Workshop attendees will be assembled in smaller, facilitated groups to promote 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 that 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.
Networking Reception in Exhibit Area

TUESDAY, OCTOBER 3 AGENDA

7:00 a.m. – 4:15 p.m.
Registration Open

7:00 a.m. – 8:30 a.m.
Continental Breakfast

8:30 a.m. – 10:00 a.m.
P5: Industry and Regulatory Challenge Topic Debate: Part 1
Moderator: Hal Baseman, Chief Operating Officer, *ValSource, LLC*

Session Description: Day two 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 and counter-point interactive discussions with experts presenting alternate views, advantages, and potential disadvantages of selected topics. The sessions will begin with a report on two important, recently published PDA surveys: the *2017 Aseptic Processing Survey*, addressing aseptic processing in general, and *PUPSIT* (pre-use, post-sterilization integrity test). Following the survey reports, the first point/counter-point discussion will involve the relative benefits and risks of using PUPSIT in sterile product manufacturing.

8:30 a.m. – 9:00 a.m.
PDA Survey Analysis
Richard M. Johnson, President and CEO, *PDA*

9:00 a.m. – 10:00 a.m.
Pre-Use, Post-Sterilization Integrity Testing (PUPSIT): Benefits versus Risks | *Is PUPSIT worth the risk?*
Andrew Hopkins, GMP Inspector, *Medicines and Healthcare Products Regulatory Agency,* and Committee Chair of the PIC/S EMA Working Group for the Revision of Annex 1
Maik W. Jornitz, MS, CEO, *G-CON Manufacturing, Inc.*

9:45 a.m. – 4:15 p.m.
Exhibit Area Open

10:00 a.m. – 10:45 a.m.
Refreshment Break in Exhibit Area

10:45 a.m. – 12:45 p.m.
P6: 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 Container Closure Integrity (CCI) | *Should CCI be used as release criteria?*
Derek Duncan, PhD, Director and Vice President, Marketing, *LIGHTHOUSE Instruments*

11:15 a.m. – 11:45 a.m.
Decision Tree on the Use of Vaporized Hydrogen Peroxide (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 Product, *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 Baroni, Director, QC Microbiology & EM/Sterility Assurance, *Eli Lilly and Company*

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

TUESDAY, OCTOBER 3 (CONTINUED)

12:45 p.m. – 2:00 p.m.
Networking Luncheon

2:00 p.m. – 3:30 p.m.
P7: Breakout Session 2
Moderator: Gabriele Gori, Head of Global Audit and Risk Management, Quality Vaccines, *GSK Vaccines*

Session Description: Attendees will break out into groups to debate some of the key issues addressed in the previous sessions. This session will include a number of specific questions for discussion and members of the Program Planning Committee will facilitate to try to develop consensus. The results of discussions from both breakout sessions will be collated and shared with the audience at the end of this session.

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

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

4:15 p.m. – 5:00 p.m.
P8: 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 who will participate in an interactive discussion regarding key topics on the Annex 1 draft revision.

Panel Discussion
Hal Baseman, Chief Operating Officer, *ValSource, LLC*
Gabriele Gori, Head of Global Audit and Risk Management, Quality Vaccines, *GSK Vaccines*
Andrew Hopkins, GMP Inspector, *Medicines and Healthcare Products Regulatory Agency,* and Committee Chair of the PIC/S EMA Working Group for the Revision of Annex 1
Regulatory Representative Invited

5:00 p.m.
Closing Remarks from Program Planning Committee Co-Chair
Gabriele Gori, Head of Global Audit and Risk Management, Quality Vaccines, *GSK Vaccines*

Connect with Industry Leaders

The *2017 PDA Annex 1 Workshop* will bring together a wide variety of industry professionals to learn about and discuss the much-anticipated and highly influential Annex 1 revision. Take advantage of this diverse group and put your brand and products in front of your ideal audience. High-profile exhibition packages and sponsorships are available for lanyards, notepads, tote bags, pens, refreshment breaks, luncheons and the Networking Reception. Don't miss this opportunity to strengthen brand image and increase visibility.

For exhibit and/or sponsorship information, please contact:

David Hall, Vice President, Sales
Cell: +1 (240) 688-4405 | Email: hall@pda.org

Alison Caballero, Senior Coordinator, Sales
+1 (301) 656-5900 ext. 135 | Email: caballero@pda.org

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2017 PDA Annex 1 Workshop

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Four easy ways to register –
Click: www.pda.org/2017Annex1
Fax: +1 (301) 986-1093 (USA)
Mail: PDA Global Headquarters
4350 East West Highway, Suite 600
Bethesda, MD 20814 USA
Call: +1 (301) 656-5900 ext. 115

Print

PDA® Parenteral Drug Association

1 Contact Information

PDA Membership Number

Prefix First Name Last Name

Job Title Company

Business Address

City State/Province ZIP+4/Postal Code

Country Email

Business Phone Fax

❒ Substituting for

(Check only if you are substituting for a previously enrolled colleague. The fee difference in the prevailing rate is due at the time of substitution. Please note that if you are a non-member substituting for a member, you will be required to pay the difference in the non-member fee.)

Special Dietary Requirements (Please be specific):

Please note: In order to receive the prevailing rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.

❍ **Check here to become a member and receive the member price for this event.** (Add $279 to your total.)

2 WORKSHOP Registration | October 2-3 *Please check appropriate fee (US$).*

		Before Jul. 25, 2017	Jul. 25 – Aug. 21, 2017	After Aug. 21, 2017
	PDA Member	❍ $ 1,895	❍ $ 2,095	❍ $ 2,295
	Non-member	❍ $ 2,174	❍ $ 2,374	❍ $ 2,574
Government/Health Authority	Member	❍ $ 700	❍ $ 700	❍ $ 700
	Non-member*	❍ $ 800	❍ $ 800	❍ $ 800
Academic	Member	❍ $ 700	❍ $ 700	❍ $ 700
	Non-member*	❍ $ 800	❍ $ 800	❍ $ 800
Student	Member	❍ $ 280	❍ $ 280	❍ $ 280
	Non-member*	❍ $ 310	❍ $ 310	❍ $ 310

* For this member type or discounted rate, online registration is not available and must be faxed in.

3 Payment Options *All cards are charged in US$.*

Group Registration: Register 4 people from the same organization as a group (at the same time) for the WORKSHOP and receive the 5th registration free. Other discounts cannot be applied. All forms MUST be faxed in together.

❍ By Credit Card – Clearly indicate account number, expiration date and billing address.
Total amount $

Please bill my: ❍ American Express ❍ MasterCard ❍ VISA
❍ Credit Card Guarantee Only

Account Number Exp. Date

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Billing Address (must match credit card statement)

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Country

Wire Transfer Payments: If you require wire transfer, please contact registration@pda.org.

CONFIRMATION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice, please be advised that a credit card guarantee is needed. Please be advised that if your payment or written cancelation notice is not received by **August 3, 2017**, your credit card will be charged the prevailing rate. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including on-site at the prevailing rate. If you are a non-member substituting for a member, you will be required to pay the difference in the non-member fee. If you are pre-registering as a subsitute attendee, indicate this on the registration form. **REFUNDS:** Refund requests must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted). **Refunds for Workshop/Event:** If your written request is received on or before **August 3, 2017**, you will receive a full refund minus a $200 processing fee. After that time, no refunds or credit requests will be approved. Onsite registrants are not guaranteed to receive Workshop materials until all advanced registered attendees receive them. PDA reserves the right to modify the material or speakers/instructors without notice or to cancel an event. If an event must be canceled, registrants will be notified by PDA in writing as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancelation. For more details, contact PDA at info@pda.org or +1 (301) 656-5900. **PLEASE NOTE THAT PHOTO ID WILL BE REQUIRED IN ORDER TO PICK UP BADGE MATERIALS ON-SITE. THIS IMPORTANT SECURITY PROCEDURE WILL PREVENT ANYONE OTHER THAN THE REGISTRANT FROM PICKING UP THEIR BADGES AND MATERIALS. RECORDING/PHOTO RELEASE:** By registering for these events, I authorize PDA to record and photograph me and to use the recordings/photographs in all formats and media for any purpose, including for education, marketing and trade purposes. I hereby release PDA from all claims arising out of the use of the recordings/photographs, including without limitation all claims for compensation, libel, invasion of privacy or violation of copyright ownership. Tape recordings are prohibited at all PDA conferences.

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