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The Parenteral Drug Association presents the...

PDA Single Use Systems Workshop

*Knowledge Enables
Implementation -
A Consensus Approach*

April 18-19, 2012

JW Marriott Desert Ridge Resort
Phoenix, Arizona



www.pda.org/singleuse2012

This preliminary agenda is current as of November 21, 2011.

Photos courtesy of Sartorius Stedim Biotech

“I found the PDA SUS workshop informative and non-commercial. Topics were relevant to the industry and solving issues which face SUS applications.”

Ken Baker,
NewAge AdvantaPure



Program Planning Committee

Co-Chairs, Program Planning Committee

Morten Munk
CMC Biologics A/S

Robert Repetto
Pfizer, Inc.

Jason E. Brown
PDA

Rich Levy, PhD
PDA

Jerold Martin
Pall Corporation

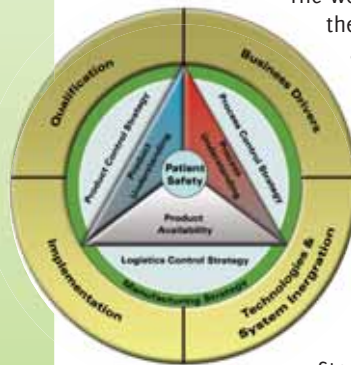
Paul Priebe
Sartorius Corporation

Georg Roesslering, PhD
PDA

Christopher J. Smalley, PhD
Merck

A Message from the Program Chairs

The PDA Taskforce for Single- Use Systems is completing a Technical Report on the implementation of Single-Use Systems and would like to invite you to attend the *PDA Single-Use Systems Workshop* on April 18-19, 2012 at the JW Marriot Desert Ridge Resort in Phoenix, Arizona, following the 2012 PDA Annual Meeting. The theme of this year's PDA Annual Meeting is *Manufacturing Innovation: Achieving Excellence in Sterile and Emerging Biopharmaceutical Technology*. To register for both the conference and the post-conference workshop please see the registration form on page 5.



The workshop will showcase and encourage the philosophies championed in the Technical Report and will offer a different approach, presenting science and risk-based concepts which are flexible and can be applied in many different situations and organizations.

The promise of Single-Use Systems is cheaper, faster and more reliable, but the real goal is to ensure that regulators accept your process. The Taskforce has taken a consensus approach to identifying just how to make that SUS mantra a reality. One of our key messages for successful Single-Use system implementation is a transparent partnership between the Single-Use System supplier and the end user by encouraging an open science and risk-based dialog during supplier audits and evaluating SUS supply chains.

Sterilization, supplier qualification, SUS qualification and extractables and leachables of Single Use Systems is a crucial concern in implementation and the taskforce has devoted an entire section of the report to quality and regulatory topics.

The workshop has been organized to highlight this partnership theme demonstrating the values we encourage in the document.

If you can attend only one Single Use focused event this year, the *PDA Single-Use Systems Workshop* is clearly the one you should attend.

The Single-Use System Task Force was strategically designed to include end users, suppliers, industry enablers and regulators. During the workshop, it will be possible to interact with taskforce members and regulators. This unique mix of skills and expertise provides a balanced, well-vetted, consensus-driven viewpoint that ensures the educational value of the workshop.

We would like to thank the Task Force members for their participation in developing the technical report and workshop. The debates and discussions about how best to implement Single-Use Systems has been outstanding. The hard work, creative ideas and dedication this group has demonstrated will make this an event not to miss.

If you would like to learn more about Single-Use Systems, be sure to register for this event! Visit www.pda.org/singleuse2012 for more information.



Morten Munk,
CMC Biologics A/S



Robert Repetto,
Pfizer, Inc.

Wednesday, April 18-Thursday, April 19, 2012 Agenda

Wednesday, April 18, 2012

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

1:00 p.m. – 2:30 p.m.

**Opening Plenary Session:
Technical Report (TR) Overview**
Moderator: **Paul Priebe**, Director of Marketing, *Sartorius Corporation*

The Opening Plenary Session will set the stage for the workshop with presentations by the co-chairs of the Single Use System Task Force describing the Technical Report document concept, structure and key themes. The Technical Report was created keeping in mind the decision process for examining the business drivers, product considerations, logistical requirements and green manufacturing goals. The presentation on Section 3 will describe the flexible approach for the Technical Report reader to utilize in the decision process to establish a manufacturing strategy.

1:00 p.m. – 1:30 p.m.

Technical Report Concepts and Themes
Robert Repetto, Director, External Affairs, *Pfizer, Inc.*

1:30 p.m. – 2:00 p.m.

Section 3 Overview
Morten Munk, Vice President, Business Development, *CMC Biologics A/S*

2:00 p.m. – 2:30 p.m.

Question and Answer

2:30 p.m. – 3:00 p.m.
Refreshment Break

3:00 p.m. – 5:00 p.m.

**Plenary Session 2:
Section 6 Part 1 – Qualification**
Moderator: **Robert Repetto**, Director, External Affairs, *Pfizer, Inc.*

Qualification is a crucial concern in implementing Single Use Systems. Certainly the concerns regarding extractables and leachables are a major part of the qualification, a FDA expert is invited to speak on the requirements defined in the Technical Report. Because Single Use Systems are frequently received by the user sterilized and ready-to-use, supplier qualification is a decisive measure in the qualification process, and in presenting the Technical Report section on supplier qualification the roles and responsibilities of the supplier and the user in the qualification effort will be discussed.

**Plenary Session 2:
Section 6 Part 1 – Qualification (Continued)**

3:00 p.m. – 3:30 p.m.

Extractable & Leachable
FDA presenter invited

3:30 p.m. – 4:00 p.m.

Supplier Perspective on Qualification
Niels Guldager, Senior Consultant, *NNE Pharmaplan*

4:00 p.m. – 4:30 p.m.

User Perspective on Qualification
Duncan Low, PhD, Scientific Executive Director, *Amgen, Inc.*

4:30 p.m. – 5:00 p.m.

Question and Answer

5:00 p.m. – 6:00 p.m.
Networking Reception

Thursday, April 19, 2012

7:30 a.m. – 8:30 a.m.

Continental Breakfast

7:30 a.m. – 3:45 p.m.

Registration Open

8:30 a.m. – 10:00 a.m.

**Plenary Session 3:
Overcoming Technology Challenges**
Moderator: **Georg Roessling**, PhD, Senior Vice President, Europe, *PDA*

This session will discuss various single use technologies and their impact on end user projects. Highlighting how end users have approached single use systems, what advantages were obtained and what challenges are on the horizon for the industry will be discussed.

8:30 a.m. – 9:00 a.m.

Perception vs Reality on Single Use Technology
Paul Priebe, Director of Marketing, *Sartorius Corporation*

9:00 a.m. – 9:30 a.m.

End User Case Study
Russell Wong, PhD, Manufacturing Sciences, *Bayer HealthCare LLC.*

9:30 a.m. – 10:00 a.m.

Question and Answer

10:00 a.m. – 10:30 a.m.
Refreshment Break

10:30 a.m. – 12:00 p.m.

**Plenary Session 4:
Section 7 – Implementation**
Moderator: **Rich Levy**, PhD, Senior Vice President, Science and Regulatory Affairs, *PDA*

A well-planned and thorough implantation plan is the key for successful implementation of SUS. This session will aim to provide an overview of areas to be included in an implementation plan around the main themes of stakeholder management, risk management and process validation and verification. Areas to be addressed include: SUS strategy, scoping, user requirements, environmental and safety considerations, materials management and supplier selection and qualification and the workflows involved.

10:30 a.m. – 11:00 a.m.

Implementation of Single Use Systems
Stephen Brown, PhD, Chief Technology Officer, *Vivalis*

11:00 a.m. – 11:30 a.m.

Implementing Single Use Systems in a GMP Environment
Robert Shaw, Technical Director, *Ark Therapeutics (Invited)*

11:30 a.m. – 12:00 p.m.

Question and Answer

12:00 p.m. – 1:15 p.m.
Networking Luncheon

1:15 p.m. – 3:15 p.m.

**Plenary Session 5:
Section 5 – Business Drivers**
Moderator: **Niels Guldager**, Senior Consultant, *NNE Pharmaplan*

The business drivers for introducing SUS are varied and depend on process, products, market, facilities as well as the general business model applied. While common business drivers are greater flexibility, facility utilization and reduced capital and operating costs, different business models create drivers for different business models. This session will cover numerous business drivers and considerations for Single Use Systems implementation.

1:15 p.m. – 1:45 p.m.

Business Drivers for the Adoption of Single-Use Technologies/Models and Considerations
Jerold Martin, Senior Vice President, Global Scientific Affairs, *Pall Corporation*

Thursday, April 19, 2012 Agenda

(continued)

Plenary Session 5: Section 5 – Business Drivers (Continued)

1:45 p.m. – 2:15 p.m.

Supplier Perspective on Business Drivers
Niels Guldager, Senior Consultant, *NNE Pharmaplan*

2:15 p.m. – 2:45 p.m.

Industry Perspective on Business Drivers
Christopher J. Smalley, PhD, Associate Director, Bio/Sterile Manufacturing, *Merck*

2:45 p.m. – 3:15 p.m.

Question and Answer

3:15 p.m. – 3:45 p.m.

Refreshment Break

3:45 p.m. – 5:15 p.m.

Plenary Session 6: Regulatory Issues Related to Single Use Systems
Moderator: Christopher J. Smalley, PhD, Associate Director, Bio/Sterile Manufacturing, *Merck*

This session will ensure that the knowledge and the challenges discussed at this workshop are captured and accessible for all interested parties within the industry and the regulatory communities; it includes a presentation outlining a common SUS knowledge platform suitable for finding valid information on relevant topics within the Single Use Systems area. Furthermore, a panel consisting of the section leads for the PDA Technical Report will be available for an open discussion on how to capture the knowledge gained over the workshop in the final version of the Technical Report for Single Use Systems.

3:45 p.m. – 4:15 p.m.

Regulatory Issues Related to Single Use Systems

Tor Graberg, Head of Inspection, *Medical Products Agency (Invited)*

4:15 p.m. – 5:15 p.m.

Panel Discussion

Panelists:

Duncan Low, PhD, Scientific Executive Director, *Amgen, Inc.*

Morten Munk, Vice President, Business Development, *CMC Biologics A/S*

Robert Repetto, Director, External Affairs, *Pfizer, Inc.*

FDA panelist invited

5:15 p.m.

Closing Remarks and Adjournment

Morten Munk, Vice President, Business Development, *CMC Biologics A/S*

Robert Repetto, Director, External Affairs, *Pfizer, Inc.*

Continuing Education Credits



PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

Following full attendance, completion and submission of the appropriate evaluation forms, certificates will be mailed within four to six weeks of the event.

PDA Single Use Systems Workshop

ACPE # 0116-0000-12-024-L04-P | 0.95 CEUs

Type of Activity: Knowledge

Learning Objectives:

At the completion of this program, participants will be able to:

- Implement a risk-based decision making process for the use of Single Use Systems
- Describe the value of a partnership relation between Suppliers and End Users
- Identify flexible approaches for implementing Single Use Systems for your specific business
- Demonstrate an awareness of regulators' expectations on the application, use and validation of Single Use Systems

Who Should Attend:

This workshop will be of significant value to: SUS suppliers, plastic manufactures, end users, suppliers, regulatory or anyone who is currently frustrated by the current state of SUS's.

Single Use systems offer unique challenges for both senior management and the shop floor technician. This workshop will help all organizational levels understand the right questions to ask when trying to overcome SUS challenges and ensure the right decisions are made.

Specifically, pharmaceutical and biopharmaceutical professionals with the following responsibilities are encouraged to participate: anyone in a position to influence or change the way their organization operates | Procurement/Purchasing | Process Development | Senior Management | Regulatory | Quality | Operations

www.pda.org/singleuse2012

General Information

Three Ways to Register

1. Click www.pda.org/singleuse2012
2. Fax +1 (301) 986-1093
3. Mail PDA Global Headquarters
Bethesda Towers
4350 East West Highway
Suite 150
Bethesda, MD 20814 USA

Venue

JW Marriott Desert Ridge Resort

5350 East Marriott Drive

Phoenix, Arizona 85054

Phone: +1 (480) 293-5000

Fax: +1 (480) 293-3600

Toll-Free: +1 (800) 835-6206

www.jwdesertridgeresort.com

Rate: Single: \$264.00, plus applicable state and local taxes.

Cut Off Date: Friday, March 23, 2012

(Rooms must be secured by this date in order to receive the PDA rate and room guarantee is based on PDA rooms block.)

Housing at this hotel will be in high demand, so we strongly recommend making your reservations early.

Conference Registration Hours

Wednesday, April 18: 7:30 a.m. – 5:00 p.m.

Thursday, April 19: 7:30 a.m. – 3:45 p.m.

Dress/Attire

Business casual attire is recommended for the *PDA Single Use Systems 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 day@pda.org.

Contact Information

For Conference Inquiries:

Jason E. Brown, Senior Manager, Programs and Meetings

Tel: +1 (301) 656-5900 ext. 131

E-mail: brown@pda.org

For Registration Inquiries:

Patresa Day, Manager, Registration and Customer Service

Tel: +1 (301) 656-5900 ext. 115

E-mail: day@pda.org

For Exhibition/Sponsorship Inquiries:

David Hall, Vice President, Sales

Tel: +1 (301) 760-7373; Cell: +1 (240) 688-4405

E-mail: hall@pda.org

Post-Conference Workshop: PDA Single Use Systems Workshop

April 18-19, 2012 • JW MARRIOTT DESERT RIDGE RESORT • PHOENIX, ARIZONA

2012 PDA ANNUAL MEETING: APRIL 16-18 | EXHIBITION: APRIL 16-17 | COURSES: APRIL 19-20

Registration for the 2012 PDA Annual Meeting is fast and simple... **CLICK, FAX OR MAIL:** **CLICK:** www.pda.org/annual2012 • **FAX:** +1 (301) 986-1093 (USA)

MAIL: PDA Global Headquarters, 4350 East West Highway, Suite 150, Bethesda, MD 20814 USA

1 Contact Information

PDA Membership Number: _____

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Job Title _____

Department _____ Company _____

Mailing Address _____

City _____ State/Province _____ ZIP+4/Postal Code _____

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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.)

2 Workshop Registration | April 18-19 Please check appropriate fee (US\$).

Workshop Only	<input type="radio"/> \$ 700
Workshop In Addition to Full Conference Purchase	<input type="radio"/> \$ 550

Special Dietary Requirements (Please be specific): _____

3 Conference Registration | April 16-18 Please check appropriate fee (US\$).

	Member		Nonmember		Government/Health Authority		Academic		Student	
	Member	Nonmember*	Member	Nonmember*	Member	Nonmember*	Member	Nonmember*	Member	Nonmember*
Before February 3, 2012	<input type="radio"/> \$ 1,495	<input type="radio"/> \$ 1,744	<input type="radio"/> \$ 700	<input type="radio"/> \$ 800	<input type="radio"/> \$ 695	<input type="radio"/> \$ 795	<input type="radio"/> \$ 225	<input type="radio"/> \$ 285		
February 3 - March 6, 2012	<input type="radio"/> \$ 1,695	<input type="radio"/> \$ 1,944	<input type="radio"/> \$ 700	<input type="radio"/> \$ 800	<input type="radio"/> \$ 775	<input type="radio"/> \$ 875	<input type="radio"/> \$ 280	<input type="radio"/> \$ 310		
After March 6, 2012	<input type="radio"/> \$ 1,895	<input type="radio"/> \$ 2,144	<input type="radio"/> \$ 700	<input type="radio"/> \$ 800	<input type="radio"/> \$ 860	<input type="radio"/> \$ 960	<input type="radio"/> \$ 315	<input type="radio"/> \$ 345		

* For Government, Academic, Health Authority and Student nonmember registrations, you must mail or fax this form to PDA.

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

See the [registration fees online](#) for pricing on networking events, group registration discounts and information on the spouse program.

4 Payment Options All cards are charged in US\$.

By Credit Card - Clearly indicate account number and expiration date and billing address.

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Total amount \$ _____

Credit Card Guarantee Only

Account Number _____ Exp. Date _____

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PDA Federal Tax I.D. #52-1906152

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 cancellation notice is not received by **February 16, 2012** 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 pre-registered as a substitute attendee, indicate this on the registration form. 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. **REFUNDS:** Refund requests must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted). **Refunds for Conference/Event:** If your written request is received on or before **February 16, 2012**, you will receive a full refund minus a \$200 processing fee. After that time, no refunds or credit requests will be approved. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. **EVENT/COURSE CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be cancelled, 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 cancellation. For more details, contact PDA at info@pda.org or +1 (301) 656-5900.

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PDA Single Use Systems Workshop
*Knowledge Enables Implementation -
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PDA Single Use Systems Workshop

Knowledge Enables Implementation - A Consensus Approach

April 18-19, 2012 | JW Marriott Desert Ridge Resort | Phoenix, Arizona

**Preliminary
Agenda
Inside**

Sponsorship and Exhibit Opportunities are Available!

High impact, cost-effective sponsorship and exhibition packages are available for the *PDA Single Use Systems Workshop*. Gain on-site exposure and connect with industry experts from manufacturing, process development, procurement, operations, quality, senior management, and regulatory agencies. The workshop agenda provides ample time for exhibitors to make new contacts and network with attendees who will be seeking solutions and guidance on single-use (disposable) technology as a proven alternative to standard, reusable stainless steel systems. Exhibit at this workshop to gain new business relationships, connect with key players in the industry, and improve your sales. In addition, comprehensive sponsorship packages will provide your company with the opportunity to strengthen brand image, increase visibility, and reinforce its commitment to the biopharmaceutical industry. Sponsorships are also available for lanyards, USBs, notepads, pens, refreshment breaks, lunch, and networking reception.

For more information about exhibit and sponsorship opportunities, please contact:

David Hall, Vice President, Sales
Direct: +1 (301) 760-7373 | Cell: +1 (240) 688-4405 | E-mail: hall@pda.org

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