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PDA Single Use Systems Workshop
Knowledge Enables Implementation - A Consensus Approach
April 18 - 19, 2012 | Phoenix, Arizona

Program 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 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*

2:00 p.m. - 2:30 p.m.

Question and Answer

Poster Presentations in Exhibit Area

Pharmaceutical Manufacturer's Approach to Qualification of Sing-Use Systems

Ken Wong, Senior Analytical Chemist, *Merck and Company*

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

3:00 p.m. - 3:30 p.m.

Extractables & Leachables

Ingrid Markovic, PhD, Expert Review Scientist, *CDER, FDA (via teleconference)*

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: Section 4 - Technology

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

8:30 a.m. - 9:00 a.m.

Technology Overview

Jeffrey Carter, PhD, Director, Filtration Research and Development, GE Healthcare

9:00 a.m. - 9:30 a.m.

Perception vs Reality on Single Use Technology

Paul Priebe, Director of Marketing, Sartorius Corporation

9:30 a.m. - 10:00 a.m.

End User Case Study

Russell Wong, PhD, Manufacturing Sciences, Bayer HealthCare LLC

10:00 a.m. - 10:10 a.m.

Question and Answer

10:10 a.m. - 10:40 a.m.

Refreshment Break

10:40 a.m. - 12:20 p.m.

Plenary Session 4: Section 7 - Implementation

Moderator: Rich Levy, PhD, Senior Vice President, Science and Regulatory Affairs, PDA

A well-planned and through implantation plan is 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

10:40 a.m. - 11:10 a.m.

Implementation of Single Use Systems

Stephen Brown, PhD, Chief Technology Officer, Vivalis

11:10 a.m. - 11:40 a.m.

Implementing Single Use Systems in a GMP Environment

Robert Shaw, Technical Director, *Ark Therapeutics*

11:40 a.m. - 12:10 p.m.

Design, Construction, Start-up and Operation of a Single-use Clinical cGMP Manufacturing Facility

Andy Walker, PhD, Senior Director, Manufacturing, *CMC Biologics*

12:10 p.m. - 12:20 p.m.

Question and Answer

12:20 p.m. - 1:20 p.m.

Networking Lunch

1:20 p.m. - 3:05 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 business common drivers are greater flexibility, facility utilization and reduce 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

1:20 p.m. - 1:30 p.m.

Introduction to Section 5

Niels Guldager, Senior Consultant, *NNE Pharmaplan*

1:30 p.m. - 2:00 p.m.

Business Drivers for the Adoption of Single-Use Technologies/Models and Considerations

Jerold Martin, Senior Vice President, Global Scientific Affairs, *Pall Life Sciences*

2:00 p.m. - 2:30 p.m.

Industry Perspective on Business Drivers

Christopher J. Smalley, PhD, Associate Director, Bio/Sterile Manufacturing, *Merck*

2:30 p.m. - 3:00 p.m.

Question and Answer

3:00 p.m. - 3:30 p.m.

Refreshment Break

3:30 p.m. - 5:00 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 provide a presentation highlighting the regulatory perspectives and concerns with the design, implementation and use of Single Use Systems, and offer attendees the opportunity to more fully engage key presenters in a panel discussion on the strategy, impact and advantages to utilization of Single Use Systems. These key presenters participating in the panel discussion have been section leads for the chapters in the draft PDA Technical Report, or key authors and bring a wealth of knowledge and experience with Single Use Systems to share with the attendees. If your questions have not been answered during the earlier presentations, this is your opportunity to ask the experts!

3:30 p.m. - 4:00 p.m.

Regulatory Issues Related to Single Use Systems

Tor Graberg, Chair of PIC/s and Head of Inspection, *Medical Products Agency (MPA)*

4:00 p.m. - 5:00 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*

FDA panelist invited

5:00 p.m.

Closing Remarks and Adjournment

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

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