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Barrier Isolation Technology

New Technologies, Case Studies and Current Applications in the Usage of Isolator Systems

JANUARY 12-13, 2009, RADISSON-PLAZA WARWICK, PHILADELPHIA, PA

Featuring Case Studies and Lessons Learned from Industry Experts!

- **Strategies for Assessing Isolator Performance and Containment Effectiveness**
- **Performing Sterility Testing and Environmental Monitoring within an Isolator System**
- **Case Studies and Design Considerations for Clinical Scale Aseptic Filling**
- **Containment Solutions for Closed Vial Technologies and Evaluating Isolator vs. RABS Technologies**
- **Decontamination of Isolators and Validating Glove Integrity**
- **Examining Blow/Fill/Seal Insert Technology**
- **Facility Design Considerations and Strategies for Process Equipment Integration**
- **Exploring Electron Beam Technologies**

Plus In-depth Session:

Evaluating Contamination Concerns for Aseptic Manufacturing and Sterility Test Isolators

Ken Muhvich, Ph.D., Principal Consultant, Micro-Reliance LLC

Featuring Representation From:

Advanced Electron Beams
Aseptic Barrier Systems LLC
DSM Pharmaceuticals, Inc.
Isogen LLC.
SafeBridge Consultants, Inc.

Applied Prime Technologies
ASEPTIC Technologies
IPS
La Calhène, Inc.
STERIS Corporation

Rommelag USA, Inc
Micro-Reliance LLC
SKAN AG
Walker Barrier



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Monday, January 12, 2009

8:30 *Chairperson's Welcome and Opening Remarks*

CONTROLLING MICROBIAL CONTAMINATION

8:45 **Evaluating Contamination Concerns for Aseptic Manufacturing and Sterility Test Isolators**
Ken Muhvich, Ph.D., Principal Consultant, Micro-Reliance LLC

Isolator environments are used for aseptic production and release testing of sterile pharmaceutical products. These isolators are barriers to the most significant source of microbial contamination – human operators. If isolators are used properly, then sterile product contamination should not occur and there should be no sterility test false positive test results. However, it is often the case that, once qualified, the care and maintenance of both production and sterility test isolators is not the best. When this occurs, the result is often microbial contamination problems. This talk will provide case studies to illustrate what can happen when isolators of both types are not properly maintained.

You will learn:

- 1) The best conditions/locations in which to operate the isolators to prevent microbial contamination.
- 2) How to properly disinfect sterility test samples before transfer into the sterility test isolator.
- 3) The optimal environmental monitoring sites and frequencies to prevent microbial contamination issues.
- 4) Environmental conditions that can lead to contamination of isolators once they have been decontaminated.
- 5) Proper cleaning and sanitization of isolators to prevent microbial contamination.

10:45 *Refreshment Break*

STERILITY TESTING AND ENVIRONMENTAL MONITORING

11:00 **Sterility Testing and Environmental Monitoring within an Isolator System**
Darcy Adee, Manager, Microbiology & Sample Management, DSM Pharmaceuticals, Inc.

This session will address the advantages of sterility testing performed within an isolator system. The importance

of an environmental monitoring program and how to handle breaches and excursions will be discussed. Other topics to be included are training, handling of personnel in regard to ergonomics and extrinsic contamination, and maintaining an excellent compliance record.

12:00 *Luncheon*

ISOLATOR SUITE DESIGN

1:15 **Case Studies and Design Considerations for Clinical Scale Aseptic Filling**
Patrice Cloué, Director, La Calhène, Inc.

Within the last 10 years, isolator has been the technique of choice for aseptic filling suite, especially for small and medium production. Isolators offer containment solutions for aseptic and/or toxic product handling and are now common in the industry.

This presentation will go over several clinical scale filling suites and will show the different possible approaches in the isolator suite design. The attendees will learn about isolator construction, component/product transfer, and classification inside the chamber for the different step of the process.

CASE STUDY PRESENTATION

2:00 **Closed Vial Technology: a Revolution in Aseptic Filling**
Benoit Verjans, Director, ASEPTIC Technologies
The closed vial technology has been developed by GSK Biologicals to address the major issues of aseptic fillings such as isolators and RABS will be illustrated. The first issue is the quality for the patient. First, many deadly accidents are recorded each year across the world due to injection of contaminated products. Second, counterfeiting is becoming a major issue for injectable drugs and the authorities such as FDA are expecting to have product traceability systems put in place. Finally, aseptic filling has reach such a complexity level due to WFI washing, sterilization, high speed stoppering, aluminum cap crimping... that an easier solution is welcomed.

The solution of the closed vial technology consists to provide a vial molded and assembled in class 100 and

gamma-irradiated. This process generates a vial clean and sterile therefore ready-to-fill. The filling process is made of a needle passing through the stopper, dispensing the liquid and withdrawn. The piercing trace is re-sealed by laser and a plastic cap is placed by snap-fit. This process increases the quality by supplying a container which stays permanently closed and therefore behaves as an isolator by it-self, and eliminates the most complex steps of aseptic filling.

As it is a new process with a new type of container, a specific containment system has been developed to address this process. This containment, called CVFS will be detailed and advantages over the classical barrier

2:45 *Refreshment Break*

ASSESSING ISOLATOR PERFORMANCE

3:00 **Measurement of Barrier Isolator and Containment Effectiveness Through the Use of Surrogate Powders and/or Active Pharmaceutical Ingredients**

Robert G. Sussman, Ph.D., DABT, Managing Principal – Eastern Operations, SafeBridge Consultants, Inc.

A proper approach to conducting a meaningful assessment of the performance of barrier isolators and other containment devices for the handling of powders and liquids including potent pharmaceutical materials will be discussed. The presentation will review the importance of conducting FAT and SAT testing for containment performance as well as worker exposure potential, the advantages and disadvantages of different surrogate materials, what to do when there is no monitoring method for the material of interest, and how to interpret data developed from such assessments.

3:45 **Decontamination of Isolators: Past, Present, Future**
Claire Fritz, VHP Process Engineer, STERIS Corporation

Isolation technology began in the 1980s. Liquid peracetic acid was one of the first decontamination methods available for isolators. Vaporized Hydrogen Peroxide (VHP®) was first introduced in 1991 by American Sterilizer Company. Many forms of the technology have been developed over the last 15 years as isolator applications have increased and expanded.

Vapor phase hydrogen peroxide remains the dominant form of decontamination for isolators due to its excellent material compatibility, efficacy, and its innocuous by-products of water vapor and oxygen.

- History of decontamination
- Process of vapor phase hydrogen peroxide
- Variables affecting efficacy
- Validation (biological indicators, real time sensors, residue analysis)
- How do you develop the fastest, most repeatable cycle?

4:30 **Case Study for the Selection, Installation and Validation of an Aseptic Isolated Pre Sterilized Tub Syringe Filling Line Utilizing eBeam Technology for Tub Surface Decontamination at Entry to the Filling Isolator**

James E. Vogel P. E., Metall + Plastic

The Objective is to provide attendees with an understanding of this approach to installing an aseptic pre sterilized tub syringe filling line.

The case study will present the key factors in the selection, installation and validation of a nested syringe tub filling line utilizing isolation and ebeam technologies. The study will summarize available technologies and will cover in significant detail a description of how the low energy ebeam technology works, applicable health and safety requirements and the ebeam decontamination process validation requirements. This is the first aseptic syringe filling line utilizing the low energy ebeam decontamination technology installed in the U. S.

The attendees will take home an understanding of the critical factors in the selection, installation and validation of an isolated tub syringe filling line utilizing eBeam technology to surface decontaminate tubs entering the filling isolator

5:15 *Close of Day One*

Tuesday, January 13, 2009

CASE STUDY PRESENTATION

8:15 **Validating Glove Integrity in Aseptic Barrier Isolators**

Dan Mohan, Ph.D., Director, Applied Prime Technologies

Use of barrier isolator technology is becoming increasingly important in aseptic manufacturing of pharmaceuticals. The integrity of gloves in such isolator systems is crucial for successful maintenance of the manufacturing process as well as assurance of product sterility. A case study representing an aseptic media fill campaign for manufacturing a drug/device combination product will be presented. Development of the acceptance criteria for the glove

leak rate and root cause failure analysis of the isolator glove assembly will be reviewed including recommendations for appropriate corrective actions.

- Glove leak testing methodologies
- Principle of SKAN glove tester
- Developing leak rate acceptance criteria
- Glove Testing scheme in an aseptic isolator campaign
- Leak rate failure modes analysis

9:15 **Glovebox Glove Training - How to Choose the Correct Gloves for your Application**

Lynn Aurelius, Manager, PIERCAN USA

Learn about the newest polymers and thermoplastics used today for the manufacturing of glove box gloves and how these new materials and hybrid gloves can help prevent punctures and loss of product and production time while protecting the operator. Understand the limits of glove materials and learn what is new in gamma irradiation of isolator gloves.

9:45 *Refreshment Break*

BLOW/FILL/SEAL TECHNOLOGIES

10:00 **Examining Blow/Fill/Seal Insert Technology**

Tim Kram, General Manager, Rommelag USA, Inc.

Blow/Fill/Seal is a 40+ year old advanced aseptic technology that has been applied to the aseptic pharmaceutical industry since the early 1970's. Conventional Blow/Fill/Seal technology is characterized by mono-layer plastic resin containers. The typically mono-layer container has a unit-dose function. Blow/Fill/Seal insert technology was developed to enable sterile filled multi-dose container format manufacturing. Insert technology utilizes an isolator and feeding systems to supply sterile parts to the Blow/Fill/Seal machine where they are placed into the Blow/Fill/Seal container and then sealed over. The entire process is performed within a controlled environment. This technology can be used to make sterile filled multi-dose vials, ophthalmic bottles, and other unique devices. This presentation examines Blow/Fill/Seal insert technology and studies the various applications the process makes possible.

10:45 **Barrier Isolator integration with the Blow/Fill/Seal Process**

Andrew Goll, Technical Sales Manager, Weiler Engineering Inc.

Blow/Fill/Seal is increasingly being recognized as an advanced form of aseptic processing by the global

regulatory community. Blow/Fill/Seal in various formats enables the end user high sterility assurance with the versatility in container design and multiple product configurations. Through the integration of a barrier isolator the range of products is ever expanding to reach broader markets and product diversity. The integration of a barrier isolator with a BFS machine utilizes pre-sterilized components and aseptically inserts these components into the Blow/Fill/Seal container. After the insertion step, the vials are hermetically sealed in one continuous operation without human intervention. This presentation will cover the integration of a barrier isolator with a Blow/Fill/Seal machine and the various product configurations that can be applied using this advanced aseptic technology. The attendees will learn about the dynamics of insertion technology; including pressure cascades, the decontamination cycle and parts containment. They will also be introduced to an end-users perspective for Environmental Monitoring, Observations and Lessons Learned.

FACILITY DESIGN CONSIDERATIONS

11:15 **Building a Process Focused Clinical Aseptic Filling Facility for Potent Compounds**

Les Edwards, CEO, Isogen LLC.

Many clinical manufacturing facilities are designed around a specific piece of process equipment or the constraints of current building layouts, which often do not lend themselves to potent compound processing. Isogen has recently converted a pharmaceutical development laboratory building into a GMP Clinical Manufacturing facility. This facility is equipped with QC Chem, QC Micro, Analytical Chemistry and Material Sciences laboratories to support the special process and product development needs of clinical manufacturing and scale-up with an eye toward facilitating tech transfer and cGMP compliance.

Using a process-based model, the presenter will discuss:

- Selecting baseline vial and syringe filling capacities
- Defining component preparation and support processes
- Sizing critical utility systems to support process equipment and constraints
- Integration of isolation technology, including a multi-use isolator platform
- Material, personnel, and process flows for containment and compliance

12:15 *Luncheon*

1:15

Facility Design for Isolator Technology Based Aseptic Processing

Sterling Kline, Director of Project Development, IPS

This presentation will cover the historical context, design philosophies, layout options, and architectural considerations for Isolator Technology Based Aseptic Facilities. It will include the practical applications of regulatory guidance including the new Annex 1. Design options will be reviewed in detail using six recent isolator projects. Examples are taken from large pharma, generic, contract and small bio manufacturers. They include liquid and lyo vials nested syringe, and BFS technologies.

- Learn practical applications of the current regulatory guidance on facility design
- Insight into isolator versus RABS technologies
- Review recent approved isolator facility designs
- Learn latest approaches to functional room classifications
- Review Annex 1 impact on capping process design

PROCESS EQUIPMENT INTEGRATION

2:00

Integrating Isolator Technology with Process Equipment

Peter Schofield, Technical Engineer, Walker Barrier

The presentation will review basic isolator technology including considering what types of products are to be produced. The size of Isolator System. The Configuration of System. Materials of Construction. Method of Decontamination or Cleaning. Material Compatibility. Laminar or Turbulent Air Flow. Manipulation-Range of Motion. Transfer of Equipment and Material. Illumination of Enclosure. The discussion will then turn to examples of isolator projects showing isolators integrated with various pieces of production, process or test equipment.

Key learning points:

- Isolator Design Considerations
- Isolator Material of Construction
- Airflow Schemes - Containment and Aseptic
- Material Handling
- Integrated Systems - fill machines, mills, freeze dryers, autoclaves etc.

2:45

Refreshment Break

3:00

Technology for Nested Syringe Filling with Focus on E-Beam for Tub Introduction

James J. Spolyar, Aseptic Barrier Systems LLC, SKAN AG Agent for the Americas

This presentation will highlight recent aseptic processing lines that have been installed for pharmaceutical syringe filling around the world, including sites at GlaxoSmithKline, Janssen (Belgium), Sanofi-Aventis (France), Novartis(Switzerland).

- Review the number of installations in Europe and the US
- Review reasons for choosing E-beam entry for tubs and other choices for entry
- Review the isolator and E-Beam design features and latest developments
- Review customer experiences in choosing isolators over a traditional clean room or Restricted Access Barrier System (RABS)

3:45

Low Energy Electron Beams for In Line Sterilization of Pharmaceutical and Medical Device Packaging

Josh Epstein, Product Manager, Advanced Electron Beams

The trend toward barrier isolator filling brings new requirements and opportunities for inline sterilization technologies. Electron beam disinfection tunnels have become the defacto standard for the transfer of nested syringe tubs into barrier isolator filling lines. The availability of compact, modular electron beam technologies opens up new opportunities beyond nested syringe tub transfer including:

- Sterile transfer of other pre-sterilized packaging components
- Direct inline sterilization of primary packaging components
- Sterile assembly of medical devices

In line electron beam sterilization offers high sterility assurance and high throughput rates while simplifying monitoring and potentially reducing the size of barrier isolator systems. What attendees will learn:

- Overview of ionizing radiation sterilization and how it relates to other in line sterilization technologies
- How low energy electron beams are currently deployed in aseptic drug manufacturing
- New opportunities for integrating electron beams into barrier isolator filling lines
- Process for evaluating electron beams for new application
- Validation considerations for deploying in line electron beams

4:30

Close of Conference



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