

PharmaED's

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Containment of Potent Compounds

Implementing Risked-Based Approaches and Ensure Safety through Strategic Containment Operations and Processes

MAY 29-30, 2008, RADISSON-PLAZA WARWICK, PHILADELPHIA, PA

Lessons Learned from Leading Industry Experts:

- **Understand the Requirements for the Containment of Potent Compounds**
- **Lessons Learned from the Field: Program Development and Implementation Steps**
- **Retrofitting Existing Equipment and Facilities to Achieve Requirements**
- **Defining Design Requirements and Achieving Innovative Design Approaches**
- **Numerous Industry Case Studies on Design, Implementation and Risk Management**

Featuring In-Depth Coverage on:

FLEXIBLE CONTAINMENT SYSTEMS

Installation, Validation and Achieving Compliance

Company Representation Includes:

**Genzyme
Floura, LLC
Ash Stevens, Inc.
Powder Systems Ltd.
Astrazeneca
Torres Placa Industrial Corporation
IES Engineers**

**Containment Solutions
Roche Colorado Corporation
Hecht Germany
ILC Dover's Containment Products
SafeBridge Consultants Inc.
Stantec Consulting Services, Inc.
Astrazeneca**



PharmaED
RESOURCES, Inc.

Thursday, May 29, 2008

8:15 *Chairperson's Welcome and Opening Remarks*

UNDERSTANDING CONTAINMENT REQUIREMENTS

8:30 **Containment Technology 101**

Hari Floura, President, Floura LLC

The pharmaceutical industry is increasingly challenged as more and more drug products are categorized as highly potent. Companies have to quickly understand the needs and technologies associated with these potent compounds and must rapidly implement controls within tight budgets. The presenter will share his 18 plus years of experience in the industry in order to provide you with the basic knowledge needed to navigate through this complex subject. Session topics will include:

- Defining your containment needs
- A brief history of exposure limits and occupational exposure banding guidelines
- PPE protection characteristics
- The available containment technologies (design, typical performances achieved, cost, advantages and disadvantages)
- The available contained transfer technologies (design, typical performances achieved, cost, advantages and disadvantages)

9:15 **Introduction to Containment of Potent Compounds**

Tomas Torres, Principal, Torres Placa Industrial Corp.

The objective of the presentation will be to provide an introduction on Containment Technology for personnel that are or will be involved in Containment Projects while providing an overall understanding on this subject. This is a practical lecture that will provide the basic know-how in containment technology, including:

- Applicable regulations
- Basics of exposure levels
- Types of containment technology
- Equipment applications

10:00 *Refreshment break*

ESTABLISHING CONTROLS

10:15 **Development and Implementation of Initial Controls for Work with Potent Compounds at a R&D Facility**

Chris Y. Ho, Ph.D., Scientific Director, Formulation Development, Genzyme Drug and Biomaterials

Recent company acquisitions and an increased interest in small molecule drug discovery created a need to work with potent compounds within existing laboratory space. This presentation will provide an overview on the program development and initial implementation steps for work involving potent compounds. Optimization of enclosure design and performance evaluation of the ventilated enclosure will be discussed. The session will conclude with a summary of a preliminary surrogate sampling study.

11:00 **Manufacture Potent APIs with Effective Process Isolation Equipment**

Rebecca Ahn Wickenheiser, Ash Stevens, Inc.

The design of a synthesis isolator suitable for the management of potent Active Pharmaceutical Ingredients (APIs) will be described. Batch size and the operations required to process an API will be discussed as will the design of the isolator. This discussion will then illustrate options for the manufacture of potent compounds using Barrier Isolation Technology at various scales. Finally, the application of this technology for the synthesis of Busulfan will be described.

Specifics topics discussed include:

- Design of scale and compound classification appropriate barrier isolation technology
- Managing regulatory requirements to move an approved process into an isolator
- Design of a chemical process using barrier isolation technology
- Cleaning requirements for the use of an isolator

11:45 *Viewing of exhibits*

12:00 *Luncheon*

FORMULATION CASE STUDY

1:30

Formulation Case Study: Retrofitting Existing Equipment to Achieve High Containment Requirements

Michelle Frisch, Sr. Manager, Global Technical Systems, Powder Systems LTD PSL

This session will present a case study on a formulation suite where engineering devices were implemented to achieve high containment of production active dispensing into IBC's. Topics covered will include:

- Retrofitting existing equipment to achieve the operator exposure limit required and weighing to a strict accuracy
- Design study protocols utilized to provide the best solution to the process requirements, addressing cross contamination issues
- Existing facility constraints which generated innovative design solutions
- Start to finish of what was implemented and how it accommodates the process including: mock-ups, process flow details, handling of different drum sizes, sampling, venting, cleaning validation, and OEL testing

FACILITY RETROFITTING

2:15

Retrofitting an Existing Facility with a Flexible Containment Area

Mike Szatmary, Principal, Containment Solutions

This case study will examine a reversed approach to retrofitting a containment area within an existing facility.

The discussion will center on the clients desire to have a "potent compound" production capability designed within the above restrictions. We will review the three available areas within the existing site. Examine the selection of production equipment and how it evolved into the building layout. Identify the allocation of funds to remain within the initial cost limitations.

Explain how future upgrades were planned to allow for lower "operator exposure levels" with minimum cost and production interruptions. The design is based on:

- Maximum production flexibility for an undetermined potent compound
- Limiting the initial cost of the retrofit to \$10,000,000.00
- Use of minimum space within the existing facility
- Upgradeable to handle increased demands of lower OEL's
- Construction time line of approximately one year

3:00

Holistic management of Risk: A Well-rounded Approach

Lesley A. Burgess, Global Industrial Hygienist, Astrazeneca

Holistic risk assesment requires a broad consideration of controls required to meet multiple business drivers. "Containment" typically evokes a vision of engineering hardware often at the sophisticated end of the engineering control spectrum eg. isolators. The views expressed in this paper encourage the use of a holistic approach to risk assessment and control. Control is considered to be a more appropriate term as this encompasses all the potential options that could be used to manage risk, "fine engineering" may or may not be among them. The critical success factor in making the right decisions about control is to use a holistic science based approach at the risk assessment stage. Multiple business drivers and factors need to be considered and experience has shown many examples where they have not been adequately considered and decisions have been made in a "vacuum"! The potential consequences of this is that health risks are not effectively managed and business needs are not met. This paper shares a wide range of examples from industry generally.

3:45

Refreshment break

CONTAINER CLOSURES

4:00

Successful Installation of Flexible Containment on Existing Pharmaceutical Processing Equipment

Jonathan Lind, Distinguished Project Engineer, Roche Colorado Corporation

Will share how existing pharmaceutical equipment was modified to provide 1-10 µg/m3 containment levels for solids handling. Examples of how flexible containment systems were installed for a variety of manufacturing operations including: dryer discharging, mill charging and discharging, reactor charging, etc., will be reviewed. Since a critical component of flexible containment systems is technique, will discuss practices which will help to ensure success. Will review successful conversion from glovebox installations to flexible containment systems for 1-10 µg/m3 requirements, and will also discuss potential to utilize these systems for even higher containment levels of 1 µg/m3 to 50 ng/m3 levels.

4:45

Close of day one

Friday, May 30, 2008

8:15 *Chairperson's Day Two Opening Remarks*

8:30 **Using Flexible Containment Technologies to Achieve Compliance**

Richard Denk, Hecht, Germany

Flexible Containment Technologies becomes more and more important due to higher requirements on cleaning from the Authorities like the FDA. Flexible Containment Technologies are most of the time designed as disposable solution and don't require cleaning. Especially for highly hazardous products where the Authorities require dedicated facilities makes it sense to use flexible disposable technologies. During the presentation the attendees get knowledge what is important to know about Flexible Containment Technologies. What risk can occur and see a real installation with that type of technology.

9:15 **SMEPAC Flexible Containment Study: Test Area Installation and Validation Followed by Initial Containment Trials**

Alan E. George, Pharmaceutical Product Line Manager, ILC Dover's Containment Products
George Petroka, IES Engineers

The Pharmaceutical industry is insisting on test data for the containment systems being considered for installation and use. This testing must be performed in a consistent and defensible manner using standard methodology. In addition, reputable third party test companies with Industrial Hygiene experience need to be contracted to perform these tests.

For the internally funded project that will be discussed, third party facility validation and testing were employed using the SMEPAC guide from ISPE, "Assessing the Particulate Containment Performance of Pharmaceutical Equipment" - 2005 Edition. This Good Practice Guide provides invaluable insight related to the main factors that affect the test results for specific contained solids handling systems including material handling, room environment, air quality, ventilation, and operator technique. This presentation will include details on the following basic scope of work:

- Clean room design and installation
- Clean room validation and certification
- Development of standard operating procedures for the clean room
- Development of industrial hygiene sampling protocols

- Industrial hygiene sampling to demonstrate the efficacy of the containment systems

10:00 *Refreshment break*

CONTAINMENT CASE STUDIES

10:15 **Potent Compound Containment Case Studies: Lessons Learned from the Field**

Dave Marsh, Industrial Hygienist, AstraZeneca

A review of techniques, equipment used to control exposure worker exposure to highly hazardous material in the workplace will be presented. The techniques and equipment described will be "traditional hard isolators", flexible containment solutions and ways of working. The case studies are from operations, R&D plants and laboratory areas.

Alongside all case studies there is industrial hygiene data generated in support of the risk assessment. The data is typically generated using a placebo such as lactose. The Industrial hygiene data demonstrates the levels of worker exposure likely when carrying out specified activities using the containment devices.

11:00 **Case Study: Containment of a Highly Active Peptide Product at an Industry Best Level of 1 ng/m³**

Leonard A. Kaufmann, Principal Project Engineer, Roche Colorado Corporation

This case study will review the design process, from conceptual design to start-up and operation, resulting in 1 ng/m³ containment of a small-scale manufacturing process for a highly potent peptide compound. Comparison to operations previously performed on laboratory benches or in hoods to new operations inside a walk-in hood and an isolator will show how various processing steps were addressed in the new design. Lessons learned from the project will be offered.

Benefits of the presentation include:

- Gain an appreciation of complex glovebox isolator design aspects
- Understand importance of modeling and mock-ups prior to fabrication
- Review examples of design simplification and impact on cleanability

12:00 *Luncheon*

HANDLING THIRD PARTY CONTRACTORS

1:15

Assessing Third Party Contract Organizations in the Handling of "Potent" Active Pharmaceutical Ingredients and Products

Allan W. Ader, Ph.D., DABT, Vice President and Principal Toxicologist, SafeBridge Consultants, Inc.

Research, development and manufacture of potent active pharmaceutical ingredients (APIs) and products requires both "hardware" (equipment, facilities and engineering controls) and "software" (programs, practices and procedures) to adequately protect personnel and the environment. When employing third party contracting organizations that may be able to technically manufacture or research the API or product to meet product needs, there is a need to evaluate this aspect to the same rigor as other aspects of drug development, such as quality assurance and product yield. Elements needed by the third party involve the recognition of the degree of hazard or risk of the API or product, evaluation through industrial hygiene assessment either qualitatively or quantitatively of the potential exposure to workers in the chemical or pharmaceutical plant, or laboratory environment, and application of appropriate containment and controls that need to be verified that exposures are below acceptable levels. This presentation will provide a systematic approach for drug innovators and contract organizations for successful resolution of issues in handling potent APIs and products.

2:00

Defining the Requirements and Setting Realistic Expectations for an OSD Potent Compound Project - An Engineers Perspective

Dave DiProspero, Principal/Practice Leader, Pharmaceutical OSD, Stantec Consulting Services, Inc.

Containment, Potent Compound Processing and cGMP Dust Control are current issues faced by nearly every OSD Pharmaceutical Manufacturer and must be adequately addressed to assure a successful project execution. This session will deal with high level planning

and adequately defining the project requirements associated with containment. By spending the time and effort up-front and developing a clear project definition and realistic expectations, many common problems, issues and budgetary overruns can be avoided.

This session will cover the following:

- What is a well-written Potent Compound Basis of Design Document and why should it be step one in the process?
- What are the key elements to include in a Potent Compound Basis of Design Document?
- From a containment standpoint what is realistic and what is pie-in-the-sky?
- Strategies for a successful Owner-Engineering Consultant-Technology Vendor Relationship, which equals a successful project

3:00

Refreshment break

IN-DEPTH PANEL DISCUSSION

3:15

Panel Discussion: Examining Current Technologies and Containment Solution Strategies: Recent Developments and Considerations

During this interactive discussion, hear faculty members discuss new developments and technologies available that have recently changed industry approaches to the containment of potent compounds.

Attendees will have the opportunity to submit questions and scenarios that will be addressed by conference faculty.

4:00

Close of conference



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About your conference destination:

The Radisson-Plaza Warwick is located in the heart of downtown Philadelphia, and adjacent to beautiful Rittenhouse Square. From the conference venue, you can access many points of interest in Philadelphia including Independence Hall, the Kimmel Center and the Avenue of the Arts and numerous shops, hotels and excellent restaurants!



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Register for the conference using one of four options:

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CONTAINMENT OF POTENT COMPOUNDS

Implementing Risked-Based Approaches and Ensure Safety through Strategic Containment Operations and Processes

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To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

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VENUE INFORMATION:

Dates: May 29-30, 2008
Hotel: Radisson Warwick Plaza Hotel
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