EuroBioConcept s.a.s
Hospital Pharmacy Isolator Systems

Presented by:

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INTRODUCTION

EBC PRODUCTS

TYPICAL INSTALLATIONS

ISOLATION TECHNOLOGY

BENEFITS

COSTS

SUMMARY
Dynamic Design Pharma, Inc.
- Founded in 2004 and based in Mission Viejo, California
- Manufacturer of accessories for isolation technology serving the Pharmaceutical and Biotech industries
- Representative of EuroBioConcept for North America

EuroBioConcept, s.a.s
- Founded in 2006 and based in Paris, France
- Manufacturer of isolator systems and associated accessories
- Over 100 isolator installations all over the world
- Major player in Hospital Pharmacy isolator systems in Europe
INTRODUCTION

Benefits of the technology
• Operator /Patient protection
• Waste elimination: reconstituted drugs
• Waste elimination: single use drugs

Regulatory drivers
• USP 797 changes
• Containment regulations

Economic Benefits
• Attractive ROI
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SUMMARY
DUAL GLOVE CAI or CACI with VHP GENERATOR

1. Low volume applications
2. Two glove/single operator
3. Positive pressure (shown) or negative pressure
4. One Pass-thru product entry
5. Air chamber product exit
6. Touchscreen control monitor
7. Waste exit port
8. Optional Rapid Transfer Port
9. Modular Vapor Hydrogen Peroxide generator
4 GLOVE CAI or CACI with VHP GENERATOR

1. Medium volume applications
2. Four gloves / two operators
3. Positive pressure or negative pressure (shown)
4. Dual Pass-thru product entry
5. Dual air chamber product exit
6. Dual Touchscreen control monitors
7. Waste exit port
8. Optional Rapid Transfer Port
9. Modular Vapor Hydrogen Peroxide generator
1. Stainless steel construction
2. Medium volume applications
3. Four gloves / two operators
4. Positive pressure or negative pressure (shown)
5. Dual Pass-thru product entry
6. Dual air chamber product exit
7. Dual Touchscreen control monitors
8. Waste exit port
9. Optional Rapid Transfer Port
10. Modular Vapor Hydrogen Peroxide generator
1. High volume applications
2. Eight gloves / four operators
3. Positive pressure or negative pressure (shown)
4. Single, High capacity Pass-thru product entry
5. Dual or Four-up air chamber product exit
6. Three Touchscreen control monitors
7. Dual waste exit ports
8. Optional Rapid Transfer Ports
9. Modular or integrated Vapor Hydrogen Peroxide generator
4 GLOVE CAI/CACI with INTEGRATED VHP GENERATOR

1. Medium volume applications
2. Four gloves / two operators
3. Positive pressure or negative pressure (shown)
4. Dual Pass-thru product entry
5. Dual air chamber product exit
6. Dual Touchscreen control monitors
7. Waste exit port
8. Optional Rapid Transfer Port
9. Integrated Vapor Hydrogen Peroxide generator
8 GLOVE CONTAINMENT COMPOUNDING ISOLATOR

1. High volume applications
2. Eight gloves / four operators
3. Positive pressure or negative pressure (shown)
4. Dual Pass-thru product entry located in rear of each module
5. Dual air chamber product exit
6. Dual Touchscreen control monitors
7. Waste exit port
8. Optional Rapid Transfer Port
9. Modular Vapor Hydrogen Peroxide generator
MODULAR / PORTABLE CLEAN ROOM

1. Clean room module for temporary installations
2. Allows quick implementation of a controlled environment
3. Configurable to any size and layout
4. Component pass-thru module
5. Personnel pass-thru module
6. Air handling system
Saint Louis Hospital – Paris, France

Public Hospital
300 preparations/day

Equipments:
2 units ChemoSafe 4 gloves in negative pressure + Large decontamination chamber – « H design »

Room classification: ISO 7
Montfermeil Hospital, France

Public Hospital
30 preparations/day

Equipment:

1 unit ChemoSafe 4 gloves in positive pressure + 1 large decontamination chamber InnoSté « H design «

Room classification: ISO 8
Monterault Hospital – France

Public Hospital
30 preparations/day

Equipment:
2 ChemoSafe 2 gloves in negative pressure with 1 decontamination chamber

Room Classification: ISO7
Hospital in Calais, France

New Public Hospital
45 preparations/day

Equipment:
1 ChemoSafe 4 gloves in negative pressure with 1 bio decontamination chamber

1 ChemoSafe 2 gloves in negative pressure with 1 bio decontamination chamber

Room classification: ISO7
Hospital in Pau, France

Public Hospital
90 preparations/day

Equipments:
1 ChemoSafe 4 gloves in positive pressure with 2 biodecontamination chamber

Room classification: ISO 8 (prefabricated building)
# Isolation Technology

- **Isolator Principles for Sterile Containment**
- **Components of a Hospital Pharmacy Isolator**
- **Product Transfer into the Isolator**
- **Product Transfer out of the Isolator**
- **Product Residuals Transfer out of the Isolator**
- **Solid Waste Disposal out of the Isolator**
- **Prescription Management**
- **Ergonomics**
- **Isolator and Room Classification**
- **Installation and Validation Requirements**
- **Maintenance (Preventive and Corrective)**
ISOLATOR PRINCIPLES FOR STERILE CONTAINMENT

Transfer Port

Air inlet

Waste disposal

Access Glove

HEPA Filters

Negative pressure leak tight chamber

Filtered exhaust
COMPONENTS OF A HOSPITAL PHARMACY ISOLATOR

- Control monitor
- Transfer Chamber
- VHP Generator
- Gloveports
- Exit airlock
- RTP Canister
- Foot rest
PRODUCT TRANSFER INTO THE ISOLATOR

VHP Generator
Transfer chamber
External door
Internal door

VHP Decontamination Facts
- Decontamination time = 30 minutes
- Validated to a SAL of $10^6$ using Apex SS B.I. coupons loaded with $10^6$ stearothermophilus spores
PRODUCT TRANSFER OUT OF THE ISOLATOR

- Beta bag with heatsealer/cutter
- Airlock chamber
PRODUCT RESIDUALS TRANSFER OUT OF THE ISOLATOR

Process

- Semi-empty single use drug container is placed in the RTP canister
- The canister is undocked and stored in a refrigerator (if needed)
- When needed, the canister is re-docked and the drug residual used again
SOLID WASTE DISPOSAL OUT OF THE ISOLATOR

- Solid waste exit port
- Solid waste exit bag
PRESCRIPTION MANAGEMENT

Basket containing all supplies and prescription router inside the transfer chamber

Prescription hung in front of the operator while she compounds the product

EBC Isolators are “certified” for integration and use with the CATO prescription management software
Operators either standing or sitting

Circulating operator

Foot rest

Basic Class D gowning: scrubs, hair nets, gloves and comfort shoes
ISO 5 = Class A = Class 100
ISO 8 = Class D = Class 100,000
INSTALLATION AND VALIDATION REQUIREMENTS

Installation

• Electrical connection
• Exhaust connection to outside atmosphere

Validation

• Factory Acceptance Test
• IQ, OQ, PQ
• VHP Cycle (with CI’s and BI’s)

Note: all installation, testing and validation protocols provided by EuroBioConcept
MAINTENANCE (PREVENTIVE AND CORRECTIVE)

Preventive (annual or semiannual)
• System overall review and repair (if necessary)
• Replacement of wear components (sleeves, gloves, gaskets)
• Calibration of all instruments

Corrective
• Critical spare parts kept in the US
• Factory trained maintenance personnel
• Emergency support from the factory also
TECHNICAL BENEFITS

OPERATOR PROTECTION

• Operator protection during potent drug compounding (containment)

PATIENT PROTECTION

• Patient protection by assuring administration of a sterile drug
• Opportunity to augment the benefits of available closed system transfer devices
ECONOMIC BENEFITS

WASTE ELIMINATION – RECONSTITUTED DRUGS

• Extension of the reconstituted drug shelf life from 6 hours to **168 hours**

WASTE ELIMINATION – SINGLE USE DRUGS

• Extension of usage of “single use” drugs from one time use (one drug per prescription) to the claimed chemical stability of the product (multi-prescription use) usually 10 days.

For reference: Annual $$ waste in a 30 chemo prescription/day hospital is $1M against a total cost of $15M (7% waste)
COSTS

CAPITAL EQUIPMENT

- Isolator system < $100K
- Compounding room miscellaneous
- Start up cost: ½ the cost of clean room

ANNUAL OPERATIONAL COSTS

- Vapor Hydrogen Peroxide bottles: $5 / Transfer load
- Sterile Bags for product exit and waste disposal: < $1 per prescription filled
- Maintenance service contracts: 10-15% of capital cost
- Spare parts (optional or as needed): 5% of capital cost
- Usually 1/5 the cost of a clean room operation
Commitment to Success

EuroBioConcept
will provide a product of superior quality that meets or exceeds your specification

Dynamic Design Pharma
will manage your project from the start to its successful implementation and support your operation for years to come
THANK YOU