ISO TECH
DESIGN

Attachment 16

August 7, 2013

STERILE COMPOUNDING

The CAI (compounding aseptic isolator) does not need to be put in an ISO Class 7 cleanroom if it meets the following conditions:
The IsoTech MicroSphere™ (CAI) maintains ISO Class 5 during dynamic operating conditions because it has unidirectional airflow in both the working chamber and the antechamber. The antechamber in the **MicroSphere™ (CAI)** is also classified ISO Class 5. The particle counts sampled 6" to 12" upstream of the critical areas is classified ISO Class 4 or better which means less than 10 particles per cubic feet. The recovery rate of the **MicroSphere™ (CAI)** is well below one minute. **The IsoTech MicroSphere™ (CAI)** has been tested according to the **CETA** isolator testing guidelines (**www.cetainternational.org**).

The attached is a certification done according to the CETA guidelines (www.cetainternational.org) that proves that the MicroSphere CAI meets all the requirements for the USP 797 and does not need to be put in an ISO 7 Clean Room.

Sincerely,

Magdy H. Moussa
President & CEO

16

1320 Graham Blvd #120, Montreal (Qc) CANADA H3P 3C8

January 2014

Personnel Cleaning and Garbing With CAI & CACI

The final **USP 797** (12/3/07) edition **(www.usp.org)** states the following that when the CAI (compounding aseptic isolator) is the source of the ISO Class 5 environment, careful cleansing of hands and arms, and correct donning of personal protective equipment (PPE) such as garments and gloves and proper disinfection procedures are required.

This should be established in the SOP (standard operating procedures).

Disinfection of gloves may be accomplished by applying 70 % IPA to all contact surface areas of the gloves and letting the gloves dry thoroughly. Routine application of 70 % IPA should occur throughout the compounding day and whenever nonsterile surfaces (e.g. vials, counter tops, chairs and carts) are touched. Gloved hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if detected, along with performing antiseptic hand cleansing as indicated above.

When CAIs and CACIs are the source of the Iso Class 5 environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any components of PPE or personnel cleansing are not required.

A study has been conducted at UMASS to prove that no gowning is required when using the MicroSphere™ CAI for sterile compounding who is in full compliance with the Final USP 797 (3/12/07) edition: "Effect of Personal Protection Equipment Utilizing Compounding Aseptic Isolators; Brown D, Nace A, Bercume R; Umass Memorial Medical Center, Worcester, Massachusetts."

Protective gowning is recommended when using the CACI for chemo compounding for operator safety.

Sincerely,

Magdy H. Moussa
President & CEO

5778 Thimens, Mtl(Qc) CAN, H4R 2K9 Tel: 800 ISO-2010, Fax:514 956-1032 email:info@isotechdesign.com

Effect of Personal Protection Equipment Utilizing Compounding Aseptic Isolators

Brown D, Nace A, Bercume R

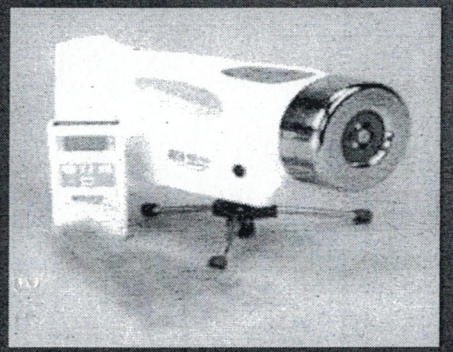
UMassMemorial Medical Center, Worcester, Massachusetts

BACKGROUND

- United States Pharmacopoeia (USP) chapter <797> establishes practice standards to ensure the quality of compounded sterile preparations.
- Proposed revisions to chapter <797> require personnel cleansing and the use of personal protection equipment (PPE) with the use of compounding aseptic isolators (CAIs).
- Documentation of validated environmental testing is needed to identify the influence of PPE upon the aseptic environment of a CAI.

OBJECTIVES

- Demonstrate the effect of personnel cleansing and PPE while compounding sterile products using CAIs.
- Provide written documentation of environmental testing to isolator manufacturer.
- Comply with USP <797> standards.
- Perform testing under normal working conditions.



Biotest RCS High Flow Air Sampler

MATERIALS AND METHODS

- High flow air sampling of 4 different sizes of positive pressure CAIs occurred.
- One thousand liters of air were sampled 6 times for each isolator using a Biotest RCS High Flow Air Sampler.
- Control air sample test was performed after cleaning.
- Subsequent 5 tests were conducted using various components of PPE.
  1. **Fully Garbed** = mask, booties, bouffant cap, and gown
  2. **W/O Mask** = booties, bouffant cap, and gown
  3. **W/O Booties** = bouffant cap and gown
  4. **W/O Hair cover** – gown
  5. **W/O Gown** = "street clothes"
- Tests with varying degrees of PPE were conducted during identical sterile compounding of a PATT 2 ™ (Personal Aseptic Technique Test).
- Makeup and jewelry were not removed prior to each test.
- Acts of personnel cleansing did not occur before each test.
- TCI-γ agar strips were incubated at 30° C-35° C for 7 days.
- Strips were visualized daily for observed growth.

RESULTS

	Micro-Sphere 12.5' X 3'	Micro-Sphere 8' X 3'	Micro-Sphere 8' X 2'	Micro-Sphere 4' X 2'
Control	No Growth	No Growth	No Growth	No Growth
1. Fully Garbed	No Growth	No Growth	No Growth	No Growth
2. W/O Mask	No Growth	No Growth	No Growth	No Growth
3. W/O Booties	No Growth	No Growth	No Growth	No Growth
4. W/O Hair Cover	No Growth	No Growth	No Growth	No Growth
5. W/O Gown	No Growth	No Growth	No Growth	No Growth

CONCLUSIONS

The sterile environment of four different models of CAIs in three separate locations were unaffected by whether or not the operators were wearing PPE. The effect of personnel cleansing and the presence of makeup, jewelry, and ear piercing had no effect on the air sampling results in the four CAIs tested.

AUTHORS AFFILIATIONS

Department of Pharmacy Services, UMass Memorial Medical Center