

## THE 2014 midyear CALIFORNIA

### Management Case Study:

**Strategies To Investigate Unacceptable Levels of Viable Air in Clean Room Environments: Minimizing Environmental Risk Factors To Compounded Sterile Preparations**

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### Learning Objectives

- Identify three structural issues that may affect viable air results in clean room environments.
- Describe five requirements for clean room certification.
- State three work practice deficiencies that may affect viable air results in clean room environments.

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### Disclaimer

The views and opinions expressed are those of the speakers and do not necessarily represent those of their organizations and any practices or policies in which they are affiliated.

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### True or False Self-Assessment Questions

- Exhaust vents located in ceilings may negatively affect viable air results in clean room environments due to "dead areas" that do not receive adequate air changes.
- Viable air results showing fungal growth are acceptable as long as action levels are not exceeded.
- Gowning and hand hygiene are not necessary in ante areas if you are not compounding.

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### Certificate of Compliance



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### Certification report should include:

- Nonviable air counts in each ISO area under dynamic working conditions
- Viable air counts in each ISO area under dynamic working conditions
- Chart showing buffer area is positive to ante area and ante area is positive to non-ISO area.
- Pressure of at least 0.02 inches of water
- 30 ACPH (15 ACPH may come from the PEC)
- Leak testing of HEPA filters
- Pertains to positive pressure ISO areas. Negative pressure ISO area requirements differ.

### Viable Airborne Particle Testing

- Collected in each ISO area under dynamic conditions
- 400 – 1000 Liters of air sample size
- Air sample for measuring bacterial load: Use TSA
- Air sample for measuring fungal load: Use MEA
- High-risk level compounding requires testing for two media: TSA and MEA (or other suitable fungal media)
- Growth identified and reported in cfu per cubic meter

TSA: Tryptic Soy Agar; MEA: Maltose Extract Agar  
cfu: Colony Forming Units

### USP <797> Recommended Action Levels for Viable Microbial Sampling of Air

- ISO Class 5 > 1 cfu
- ISO Class 7 >10 cfu
- ISO Class 8 (or worse) >100 cfu
- Per USP <797>, “Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered.”
- “Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied.”

### Investigation

- Evaluation of physical structure
- ACPH
- Pressures
- HEPA integrity
- Personnel garbing and hand hygiene
- Cleaning and disinfection procedures
- Environmental monitoring
- Aseptic technique

### Contributing Factors (Structural)

- Poor location of ante room doors
- Lack of adequate HEPA filtration
- Inadequate ACPH
- Low pressure
- Air leaks through uncaulked ceiling
- Inappropriate placement of vents
- Surfaces not smooth and/or nonshedding

### Contributing Factors (Personnel)

- Failure to perform proper garbing and hand hygiene
- Failure to disinfect gloves with sterile IPA after touching nonsterile surfaces
- Failure to stage components into each ISO area
- Inappropriate disinfectant choice
- Failure to observe disinfectant contact times

### Case Study

- Community pharmacy that performs nonhazardous high-risk level sterile compounding
- ISO 7 buffer room containing 4 ft LAFW
- ISO 8 ante room containing sink, powder-containment hood with electronic balance and limited supplies

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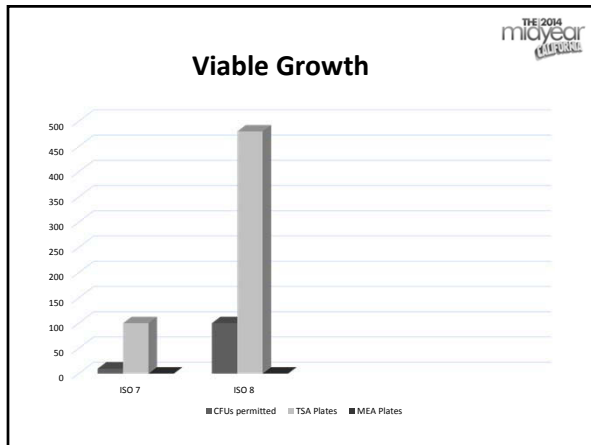
### Certification Reports Prior to June 2014

- Performed under ‘occupational’ conditions
- Nonviable and viable air counts within limits
- Pressures and pressure relationships acceptable
- Air changes per hour not reported
- Leak testing on HEPA filters not performed

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### Certification Report June 2014

- Performed under ‘occupational’ conditions
- Nonviable air counts within limits
- Viable air counts outside limits
- Pressures and pressure relationships acceptable
- Air changes per hour reported as passing
  - Buffer room 60.73 ACPH
  - Ante room 23.84 ACPH
- No leaks detected in HEPA filters



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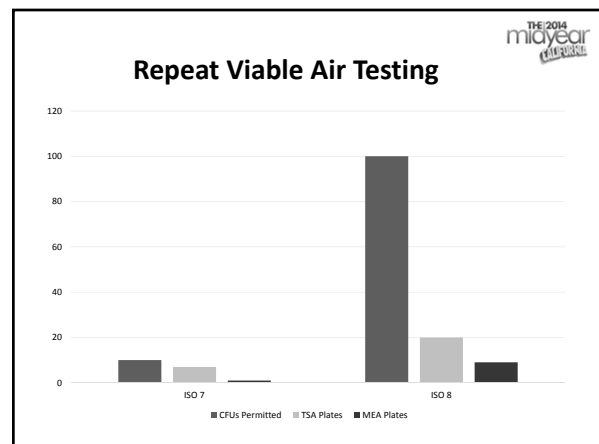
### Investigation of Work Practices

- Staff training and validations complete
- Garbing and hand hygiene acceptable
- Aseptic technique acceptable
- Staging not performed into each ISO area
- Ante room door remained open for prolonged periods
- Two disinfectants with sporicidal activity rotated
- Disinfectant contact times adequate
- Cleaning order from cleanest to dirtiest

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### Other Concerns Identified

- Certification personnel donned garb but did not perform hand hygiene
- Same garb worn in and out of ante room while bringing in certification equipment
- Ante room door left open while bringing in certification equipment
- Certification equipment not staged
- HEPA filter accessed through ceiling from ISO areas



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### Growth Identified

- ISO 7 Micrococcus 5 cfu
- ISO 7 Coag-negative staphylococcus 2 cfu
- ISO 7 Pithomyces 1 cfu
  
- ISO 8 Coag-negative staphylococcus 14 cfu
- ISO 8 Cladosporium 7 cfu
- ISO 8 Micrococcus 6 cfu
- ISO 8 Pithomyces 2 cfu

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### New Employee Break Area



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### Conclusion

- Safety of compounded sterile preparations starts with the cleanliness of clean rooms
- Knowledge of clean room certification requirements is essential
- Assess clean rooms for structural problems
- Address employee work practices

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### Recommendations

- Evaluate compounding personnel
  - garbing and hand hygiene
  - aseptic technique
  - cleaning and disinfection procedures
  - media fill testing and fingertip sampling
  - didactic training with written quiz
- Frequency of evaluations
  - every 6 months for high-risk sterile compounding
  - annually for low/medium-risk sterile compounding
- Evaluation forms available in appendix of USP<797>

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### Recommendations

- Restrict access to ante and buffer rooms
  - No non-essential personnel allowed
  - Minimize opening of ante room door
  - Only materials needed for compounding ensuring proper staging into each ISO area
- Monitor room environment and document results
  - Check of temperature, humidity and pressure by compounding staff every shift
  - Viable surface sampling in each ISO area by compounding staff
  - Every 6 months check of nonviable and viable air counts, pressure relationships, ACPH and filter integrity by contractor

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### Recommendations

- Standard operating procedures (SOPs) are written and readily accessible
  - Compounding personnel read and understand SOPs
  - SOPs reviewed annually for accuracy
- Monitor cleaning procedures
  - Consult with environmental services or microbiologist about disinfectant choice
  - Routinely rotate different types of disinfectants
  - Use a disinfectant with sporicidal activity

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### Recommendations

- Choose a reliable certification contractor
  - Performs all required USP <797> testing
  - Provides a detailed report of results
- Read the report and take appropriate actions
  - Ensure that the results are within USP <797> specifications
  - Investigate any cfu, especially if it exceeds the action levels
  - Find the source of the contamination, eliminate it, clean and disinfect the environment, and re-test

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### Self-Assessment Question 1

- Exhaust vents located in ceilings may negatively affect viable air results in clean room environments due to “dead areas” that do not receive adequate air changes.

**Answer:** True

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### Self-Assessment Question 2

- Viable air results showing fungal growth are acceptable as long as action levels are not exceeded.

**Answer:** False

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### Self-Assessment Question 3

- Gowning and hand hygiene are not necessary in ante areas if you are not compounding.

**Answer:** False

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### Key Takeaways

- Key Takeaway #1
  - Constantly monitor the operations, environment, and personnel for compounding sterile preparations
- Key Takeaway #2
  - Rotate disinfectants and use a sporicidal
- Key Takeaway #3
  - Document and review all test results, environmental readings, cleaning procedures, and investigations

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## Thank You!

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