(Management Case Study)
UV-C Improves Pharmacy Air Quality and USP 797 Compliance

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Disclosure

Linda Lee
American Green Technology: Employee

All other planners, presenters, and reviewers of this session report no financial relationships relevant to this activity.
Learning Objectives

• Review the USP 797 sampling requirement.
• Explain the role of UV-C in improving air quality and reducing airborne bacteria and fungus.
• List the types of sampling agars for viable bacteria and fungus.
Self-Assessment Questions

1. (True or False) Part of the overview of USP 797 sampling requirements include sampling for viable fungus.

2. (True or False) USP 797 requires taking action in your ISO class 5 room if you measure more than 1 CFU per cubic meter of air.

3. (True or False) Malt Extract Agar (MEA) is used to sample bacteria.
Multistate fungal meningitis outbreak in 2012

- Linked steroid injections
- 753 cases affected
- 20 states
- 64 deaths

Source: https://www.cdc.gov/hai/outbreaks/meningitis.html
What is USP 797?

- USP 797 refers to chapter 797 “Pharmaceutical Compounding - Sterile Preparations” in the USP National Formulary. It is the first set of enforceable sterile compounding standards issued by the United States Pharmacopeia (USP).
- It describes the guidelines, procedures and compliance requirements for compounding sterile preparations and sets the standards that apply to all settings in which sterile preparations are compounded.
- USP <797> applies to the compounding of both hazardous and non-hazardous drugs

Prevent Patient Harm From
- Microbial contamination
- Excessive bacterial endotoxins
- Variability in the intended strength of correct ingredients
- Unintended chemical and physical contaminants
- Ingredients of inappropriate quality
What Is The USP 797 Compliance Standard For Non-viable Particulates

• In critical areas such as Class 100 or ISO 5 (area in immediate proximity of exposed sterilized containers/closures and filling/closing operations), the particle per cubic meter must be no more than 3520 particles/m³ in a size of 0.5 micrometers or larger when counted at representative locations normally not more than 1 foot away from the work site, within the airflow, and during filling/closing operations.

• Supporting areas, or clean room areas where the laminar flow stations are located, must meet at least Class 100,000 (ISO 8) air quality.
# Clean Rooms

<table>
<thead>
<tr>
<th>Clean Air Classification</th>
<th>ISO Designation</th>
<th>&gt;0.5 μm particles/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>5</td>
<td>3,520</td>
</tr>
<tr>
<td>1,000</td>
<td>6</td>
<td>35,200</td>
</tr>
<tr>
<td>10,000</td>
<td>7</td>
<td>352,000</td>
</tr>
<tr>
<td>100,000</td>
<td>8</td>
<td>3,520,000</td>
</tr>
</tbody>
</table>
Non-Viable Particulates

• The nature of your activities conducted in a supporting clean room area determines its classification.

• FDA recommends that the area immediately adjacent to the aseptic processing line meet, at a minimum, Class 10,000 (ISO 7) standards under dynamic conditions.

• Manufacturers can also classify this area as Class 1,000 (ISO 6) or maintain the entire aseptic filling room at Class 100 (ISO 5).

• An area classified at a Class 100,000 (ISO 8) air cleanliness level is appropriate for less critical activities (e.g., equipment cleaning).
USP 800 Key Aspects

• Maintain list of hazardous drugs - review annually.
• Types of exposure and staff responsibilities when handling hazardous drugs - Designate compounding supervisor
• Facilities: receipt, storage, compounding and containment supplemental engineering controls.
• Environmental Quality and Control - Surface wipe sampling every 6 months.
• Personal Protective Equipment
• Hazard communications, personnel training
• Labeling, packaging and transport, dispensing final dosage forms, compounding and administering
• Deactivation/decontamination, cleaning and disinfection, spill control, disposal, documentation and standard operating procedures

Medical Surveillance
• Minimize adverse health effects in persons potentially exposed to hazardous drugs
• Proactive approach for early detection of health problems that compares trends overtime with an employee’s baseline health status
Pharmacy Case Study

- Located in Memphis, Tennessee
- Freestanding hospital with 255 beds
- Part of the larger Healthcare System
- Each year, the hospital treats over 250,000 patients from across the country and world
- 2780 total pharmacy orders/day
- 44 compounding pharmacists; 45 compounding technicians
Barriers to Compliance

USP 797 common non-compliant issues

• Facility design and workflow
• Ceiling penetration issues
• Lack of proper cleaning and disinfection
• Lack of environmental testing and follow up
Pharmacy Case Study

Protocol for Pre-Installation Testing

- Pre-installation testing conducted fall of 2016
- Independent third party collected all samples
- Air sampling - SAS 180 high volume impingement air sampler.
- Surface sampling - Rodac type contact plates
- Bacteria samples - TSA with blood (tryptic soy agar) plates
- Fungus samples - MEA (malt extract agar) plates
Pharmacy Case Study

Testing Areas

• Pharmacy work space  5152 square feet
• Clean room   264 square feet
• Ante Room    600 square feet
• Chemo Room   88 square feet
Pharmacy Case Study

Sample Locations for Pre-Installation Testing

• Anteroom
• Break room
• Storage room
• Work rooms
• IV room
• Chemotherapy prep room
• Interior & Exterior Hallways
Sampling Process

Rodac Plates

Blood Agar Plates
Installation Process
Dispensing & Processing

Ante Room

Receiving
Protocol for Post-Installation Testing

- Post-installation testing (once all units were installed) was conducted in spring of 2017.
- Independent lab analyzed the samples for total bacterial and fungal counts.
- Samples were handled as required.
- All counts were noted and recorded.
- An correction was performed for all air sampling samples using the SAS 219-hole impactor correction hole factor.
Results

Fungi Air Sampling

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.30</td>
<td>1.82</td>
</tr>
<tr>
<td>Reduction</td>
<td>78%</td>
<td></td>
</tr>
</tbody>
</table>

Bacteria Air Sampling

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>56.72</td>
<td>21.79</td>
</tr>
<tr>
<td>Reduction</td>
<td>62%</td>
<td>21.79</td>
</tr>
</tbody>
</table>

Overall 78% reduction in bacteria & 53% in fungi.
## Results - Anteroom

<table>
<thead>
<tr>
<th></th>
<th>Pre CFUs</th>
<th>Post CFUs</th>
<th>% Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fungi</td>
<td>1.8</td>
<td>0.18</td>
<td>90%</td>
</tr>
<tr>
<td>Bacteria</td>
<td>35.3</td>
<td>4.85</td>
<td>86%</td>
</tr>
</tbody>
</table>
## Air Fungal Data

<table>
<thead>
<tr>
<th>Location</th>
<th>Mean CFU/m³ Pre-installation</th>
<th>Mean CFU/m³ Post-installation</th>
<th>Mean CFU/m³ Change</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exterior Hall</td>
<td>10.75</td>
<td>14.10</td>
<td>+3.375</td>
<td>-11.64, 4.89</td>
<td>0.396</td>
</tr>
<tr>
<td>IV Rm (ISO 7)</td>
<td>3.25</td>
<td>0</td>
<td>-3.250</td>
<td>-4.44, 10.94</td>
<td>0.351</td>
</tr>
<tr>
<td>Chemo Rm (ISO 7)</td>
<td>2.25</td>
<td>0.38</td>
<td>-1.875</td>
<td>-0.70, 4.45</td>
<td>0.131</td>
</tr>
<tr>
<td>Interior Hall</td>
<td>10.50</td>
<td>2.14</td>
<td>-8.71</td>
<td>3.04, 14.39</td>
<td>0.008</td>
</tr>
<tr>
<td>Breakroom</td>
<td>11</td>
<td>2.50</td>
<td>-8.50</td>
<td>3.92, 13.08</td>
<td>0.003</td>
</tr>
<tr>
<td>Storage Rm</td>
<td>25.6</td>
<td>2.60</td>
<td>-23</td>
<td>-9.68, 55.68</td>
<td>0.140</td>
</tr>
<tr>
<td>Ante-Rm (ISO 7)</td>
<td>1.8</td>
<td>0.18</td>
<td>-1.56</td>
<td>0.63, 2.50</td>
<td>0.003</td>
</tr>
<tr>
<td>Work area one</td>
<td>11.5</td>
<td>6.10</td>
<td>-5.50</td>
<td>-3.67, 14.67</td>
<td>0.219</td>
</tr>
<tr>
<td>Work area two</td>
<td>7</td>
<td>2.25</td>
<td>-4.75</td>
<td>0.55, 8.95</td>
<td>0.031</td>
</tr>
<tr>
<td>Overall</td>
<td>8.30</td>
<td>1.82</td>
<td>-6.48</td>
<td>2.78, 10.17</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
## Results – IV Compounding Room

<table>
<thead>
<tr>
<th></th>
<th>Pre CFUs</th>
<th>Post CFUs</th>
<th>% Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fungi</td>
<td>3.25</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Bacteria</td>
<td>1.5</td>
<td>0.125</td>
<td>92%</td>
</tr>
</tbody>
</table>
## Air Bacteria Data

<table>
<thead>
<tr>
<th>Location</th>
<th>Mean CFU/m³ Pre-installation</th>
<th>Mean CFU/m³ Post-installation</th>
<th>Mean CFU/m³ Change</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exterior Hall</td>
<td>95.13</td>
<td>59.8</td>
<td>-35.38</td>
<td>14.00,84.75</td>
<td>0.141</td>
</tr>
<tr>
<td>IV Rm (ISO 7)</td>
<td>1.5</td>
<td>0.125</td>
<td>-1.38</td>
<td>0.36,2.39</td>
<td>0.014</td>
</tr>
<tr>
<td>Chemo Rm (ISO 7)</td>
<td>27.6</td>
<td>8</td>
<td>-19.63</td>
<td>3.89,35,36</td>
<td>0.020</td>
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<tr>
<td>Interior Hall</td>
<td>74.3</td>
<td>74.9</td>
<td>+.063</td>
<td>-109.3,108.1</td>
<td>0.990</td>
</tr>
<tr>
<td>Breakroom</td>
<td>87.3</td>
<td>20.8</td>
<td>-66.50</td>
<td>41.48,91.52</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Storage Rm</td>
<td>110.9</td>
<td>34</td>
<td>-76.88</td>
<td>76.88,20.15</td>
<td>0.013</td>
</tr>
<tr>
<td>Ante-Rm (ISO 7)</td>
<td>35.3</td>
<td>4.85</td>
<td>-30.44</td>
<td>5.85,55.02</td>
<td>0.019</td>
</tr>
<tr>
<td>Work area one</td>
<td>86.6</td>
<td>29</td>
<td>-57.63</td>
<td>6.18,109.10</td>
<td>0.032</td>
</tr>
<tr>
<td>Work area two</td>
<td>51.8</td>
<td>19.6</td>
<td>-32.13</td>
<td>-0.01,64.26</td>
<td>0.050</td>
</tr>
<tr>
<td>Overall</td>
<td>56.72</td>
<td>21.79</td>
<td>34.93</td>
<td>18.47,51.39</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
How it Works

Air and pathogens

Returns treated air
Executive Summary

- Augment current engineering controls to improve air quality.
- Deployment shielded UV air purification technology – installation of 52 UV-C units in the pharmacy.
- 24/7 operation in occupied spaces.
- System uses UV-C light and filtration to draw in and treat environmental air.
- Preliminary study results showed statistically significant reduction in bacterial and fungal colony counts post installation of UV-C technology.
Conclusions

• In conjunction with appropriate personnel training and environmental cleaning, a UV-C air purification system can help decrease air and surface bacteria and fungal CFUs in compounding clean rooms.

• Preliminary testing has shown a significant decrease in bacteria and fungal CFUs in buffer ISO 7 areas (clean and ante rooms) when a new technology using UV-C light and filtration systems was installed to reduce air borne bacterial and fungal CFUs in areas adjacent to those ISO 7 areas.

• This is a promising use of technology, particularly with the ability to constantly filter the environmental air using the UV-C air purification.
Key Takeaways

• Key Takeaway #1
  UV-C air purification, in addition to environmental cleaning, can reduce the number of bacterial and fungal CFUs in the air in the compounding pharmacy area.

• Key Takeaway #2
  Data shows a significant decrease in bacterial and fungal CFUs in adjacent ISO 7 areas once the UV-C systems were installed in those areas.

• Key Takeaway #3
  By reducing the contamination in the anteroom, the contamination is also reduced in the compounding area.
References

5. Don Guimera, MSN, RN, CIC, CCRP, FAPIC, Jean Trzil, PharmD, Joy Joyner, RN, CIC, Nicholas D. Hysmith, MD, FAAP, Effectiveness of a shielded UV-C air disinfection system in an inpatient pharmacy of a tertiary care children’s hospital, American Journal of Infection Control, August 2017