USP <797> Changes and its Impact on Your Environmental Monitoring Program

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EM Program Manager, Element Materials Technology
The “Top 5” EM Related Changes

- The “Designated Person”
- New Compounded Sterile Preparation (CSP) Categories
- Minimum Sampling Frequencies
- Incubation and ID Requirements
- Aseptic Manipulation Competency & Hand Hygiene and Garbing
The “Designated Person”

- Develops facility SOPs
- Acts as a liaison with vendors
- Implements staff training program
- “Gatekeeper” of access into the cleanroom suite
- Responsible for compliant handling
# New CSP Categories

<table>
<thead>
<tr>
<th>USP &lt;797&gt; (2008)</th>
<th>USP &lt;797&gt; (2022)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td>Category 1</td>
</tr>
<tr>
<td>Medium Risk</td>
<td>Category 2</td>
</tr>
<tr>
<td>High Risk</td>
<td>Category 3</td>
</tr>
</tbody>
</table>
Category 1 Compounding

Primary Engineering Control (PEC) ISO 5

Segregated Compounding Area (SCA)
Category 2 & 3 Compounding

- Primary Engineering Control (PEC) ISO 5
- Non-Hazardous Buffer Room ISO 7
- Anteroom ISO 7
- Hazardous Buffer Room ISO 7
### Minimum Sampling Frequencies

<table>
<thead>
<tr>
<th>Category</th>
<th>Viable Active Air</th>
<th>Viable Surface</th>
<th>Total Particulate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Semi-Annual</td>
<td>Monthly</td>
<td>Semi-Annual</td>
</tr>
<tr>
<td>2</td>
<td>Semi-Annual</td>
<td>Monthly</td>
<td>Semi-Annual</td>
</tr>
<tr>
<td>3</td>
<td>Monthly</td>
<td>Weekly*</td>
<td>Semi-Annual</td>
</tr>
</tbody>
</table>
# Revised Viable Action Levels

<table>
<thead>
<tr>
<th>ISO Class</th>
<th>Viable Active Air</th>
<th>Viable Surface</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>&gt; 1 CFU/m³</td>
<td>&gt; 3 CFU/plate</td>
</tr>
<tr>
<td>7</td>
<td>&gt; 10 CFU/m³</td>
<td>&gt; 5 CFU/plate</td>
</tr>
<tr>
<td>8</td>
<td>&gt; 100 CFU/m³</td>
<td>&gt; 50 CFU/plate</td>
</tr>
</tbody>
</table>
Risk-Based Sampling Locations?

- **Primary Engineering Control (PEC) ISO 5**
- **Non-Hazardous Buffer Room ISO 7**
- **Anteroom ISO 7**
- **Hazardous Buffer Room ISO 7**
Risk-Based Sampling Locations? Option A

- Primary Engineering Control (PEC) ISO 5
- Hazardous Buffer Room ISO 7
- Anteroom ISO 7
- Non-Hazardous Buffer Room ISO 7
Risk-Based Sampling Locations? Option B
Routine Sampling vs. Cleaning “Spot Check”

• Based on the previous slides, which one provides the most useful information? Is one more risk-based than the other?
  • Option B, but it depends!
  • How to identify trends?

• May need to have different sampling plans for different situations
  • Leads to adoption of better work practices!

• Important to review and revise the plan over time...
Incubation and ID Requirements

- SDA media and TSA dual incubation “back half” = 20° C to 25° C
  - Fungal media requirement has been removed from the 2022 version

- Organism ID requirement is still to genus level
  - Now only if action level is exceeded

- “Highly pathogenic” focus organisms removed

- How to handle ISO 5 recoveries?
Aseptic Manipulation Competency

- Initial frequencies remain unchanged, however:
  - Post-fill surface sample of the PEC has been added

- Ongoing training for Category 1 and 2 = Semi-annual

- Requalification for Category 3 = Quarterly

- Media-fill TSB = two temperatures
  - 20° C to 25° C for 7 days, then 30° C to 35° C for 7 days

Testing Scope

- TSB Media-fill
- Post-fill DCA surface sample
- Post-fill GFT samples
The Direct Compounding Area (DCA)

Source: Aseptic Technique on YouTube
# Aseptic Manipulation Competency Action Levels

<table>
<thead>
<tr>
<th>Test</th>
<th>Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSB Media-fill</td>
<td>Any growth</td>
</tr>
<tr>
<td>Post-fill DCA surface sample</td>
<td>&gt; 3 CFU/plate</td>
</tr>
<tr>
<td>Post-fill GFT samples</td>
<td>&gt; 3 CFU (total both hands)</td>
</tr>
</tbody>
</table>
Hand Hygiene and Garbing

• Initial frequencies remain unchanged
  • Requires three separate and complete garbing and GFT samples

• Ongoing Training for Category 1 and 2 facilities = Semi-annual

• Ongoing Training for Category 3 = Quarterly

• Gloved Fingertip and Thumb Sampling (GFT) = dual temperature incubation
  • Previously only 30° C to 35° C for 48 to 72 hours
Hand Hygiene and Garbing Action Levels

<table>
<thead>
<tr>
<th>Test</th>
<th>Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial GFT (3 trials)</td>
<td>Any growth</td>
</tr>
<tr>
<td>Ongoing GFT (1 trial)</td>
<td>Any growth</td>
</tr>
</tbody>
</table>
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