INTEGRATED VPHP DECONTAMINATION SYSTEMS
THE EMERGING UTILITY

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ISPE Product Show
Track 3 Session 3
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AGENDA

1. BACKGROUND INFORMATION
2. BENEFITS
3. PROCESS
4. BEST MANAGEMENT PRACTICES
5. VALIDATION / SAFETY
6. STAKEHOLDERS
7. FAQS
Speaker

> Working with VPHP applications at Steris Corp since 2004
> Observations vs. formal testing
> Difference between integrated and portable VPHP applications

Why Use VPHP?

✓ Efficacy (Broad spectrum sterilant)
✓ Consistency & Distribution
  ➢ Reach difficult to access surfaces
  ➢ Passes through HEPA filters
  ➢ Kills airborne and surface microbes
✓ Excellent Material Compatibility
  ➢ Electronics
  ➢ Metals and common polymers
✓ Speed
  ➢ Minimal labor required
  ➢ Easy to validate
✓ Green Technology
  ➢ Low toxicity
  ➢ No residues
  ➢ EPA approved
Agent | Uses
---|---
Chlorine Dioxide | Containment, industrial, water
Atomized Hydrogen Peroxide | Service decon
Vapor Hydrogen Peroxide | Service decon, cleanrooms, isolator, packaging
Ozone | Mostly food and water
Peracetic acid | Rooms, small enclosures
Ethylene Oxide | Mostly contracted service bulk product
Methyl Bromide | Agriculture, some interest from Homeland
UV light | Room decon, packaging
E-beam | Syringe tub decon

3 Key Factors for Robust and Rapid Cycles

<table>
<thead>
<tr>
<th>Factor</th>
<th>Desired Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent Saturation</td>
<td>High percent saturation but below dew point</td>
</tr>
<tr>
<td>Concentration</td>
<td>Highest concentration without condensing</td>
</tr>
<tr>
<td>Distribution</td>
<td>Homogenous distribution</td>
</tr>
</tbody>
</table>
A D-value is the time needed to achieve a log reduction (90% kill) of the target organism.

Efficacy More than Doubles with Percent Saturation (note: a single concentration used)
### Distribution - Chemical Indicators

#### Less Distribution/Exposure

- Portable Generator (piped)
- Portable Generator (non-piped)
- Enclosure
- Airflow

#### More Distribution/Exposure

- Integrated Generator (with manifold)
- Scenarios
  - A. Inside single or networked
  - B. Outside – closed loop or single pass
  - C. Integrated single pass piped to decontaminate zone 1 or zone 2
Which VPHP System?

- **portable**
  - ✓ Spaces not yet defined
  - ✓ Uses in different buildings
  - ✓ Typically less than 6,000ft³
  - ✓ Cycle time not a constraint
  - ✓ Use of fans not an issue
  - ✓ Less frequent use

- **integrated**
  - ✓ Large and small spaces up to ~40,000 ft³ / cycle + unit
  - ✓ Same enclosures repeatedly
  - ✓ Frequent use (chamber)
  - ✓ Short cycle times
  - ✓ Automated sequenced decontamination of multiple rooms

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Common Applications

- ➢ BSL2 / BSL3
- ➢ Grade A and B / ISO 5 and 7 Rooms
- ➢ Decontamination Chambers
- ➢ RABS
- ➢ Incubators
- ➢ Isolators
- ➢ Rooms containing LAFWBs or BSCs
Connecting Pharmaceutical Knowledge

**VPHP Modular System**

- **Warm Wet Air Exhaust**
- **Iris Valve**
- **Reactivation Air Inlet**
- **Dryer**
- **Process Air Inlet / Air Inlet**
- **Dry Air Outlet**
- **Modular VHP**
- **Sterilant Outlet**
- **Manifold**
- **Room 1**
- **Room 2**

**Distribution Schematic**

- **HC-300**
- **VHP T4**
- **BMS Master Controller**
- **120 CFM E Pipe**
- **Zone 1**
- **Zone 2**
- **Manifold**
- **Balancing Dampers**
- **Injection point into common supply duct of each of the 3 AHUs per zone**

Connecting Pharmaceutical Knowledge
Control via Building Automation System

Automatización

[Diagram with labels and symbols related to control systems and automation]
Duct Interface

Manifolds

- Manual valves
- Actuated valves
Manifold

Biopharmaceutical Fermentation Suite

Volume: 32,000ft³ (900m³)

Ceiling height: 28ft (8.5m)

Single pass, No fans

6-log reduction

Cycle time 6 hours

<table>
<thead>
<tr>
<th>Cycle Phase</th>
<th>Time min.</th>
<th>Airflow g/min</th>
<th>Injection g/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dehumidification</td>
<td>30</td>
<td>6 A.E./ hour</td>
<td>-</td>
</tr>
<tr>
<td>Condition</td>
<td>30</td>
<td>120 cfm</td>
<td>96</td>
</tr>
<tr>
<td>Decontamination</td>
<td>90</td>
<td>120 cfm</td>
<td>60</td>
</tr>
<tr>
<td>Aeration</td>
<td>210</td>
<td>40 A.E./ hour</td>
<td>-</td>
</tr>
</tbody>
</table>

A.E. = Air Exchange
### Pass-Through Chambers / Transfer Hatches / Material Air Locks

<table>
<thead>
<tr>
<th>Enclosure v</th>
<th>Volume ft³</th>
<th>Enclosure surface material</th>
<th>Injection rate</th>
<th>Decon time Min</th>
<th>Decon airflow ft³/min</th>
<th>PPM</th>
<th>Aeration airflow ft³/min</th>
<th>Total Cycle Time min.</th>
</tr>
</thead>
<tbody>
<tr>
<td>460</td>
<td>(6x8x9.5'L)</td>
<td>Stainless</td>
<td>32</td>
<td>12</td>
<td>120</td>
<td>1000</td>
<td>765</td>
<td>45</td>
</tr>
<tr>
<td>175</td>
<td>(4x6x7'L)</td>
<td>Epoxy paint</td>
<td>12</td>
<td>9</td>
<td>8</td>
<td>40</td>
<td>950</td>
<td>1750</td>
</tr>
</tbody>
</table>
RABS – (Restricted Access Barrier Systems)

Modular VHP systems can rapidly decontaminate both Active & Passive RABS and the rooms they are housed in

Source: Pharmaceutical International
Integrated installations
Cycle Development / Validation

- Frequency of Use
- Effort for Set-up, Operation
- Acceptable Cycle Time
- Have I captured what I need in a URS?
- Initial and Operating Cost and lifetime cost
- Level of log reduction, Process Robustness

Stakeholders - Define & Develop Your Expectations
Take Aways

VPHP –
- Can be deployed as a utility
- Automated decontaminated sequences can run from the BAS
- Once installed and validated – minimal effort to execute cycles
- Many different enclosure types can be decontaminated
  - isolators, RABS, cleanrooms, incubators, BSCs, Chambers etc.
Once installed very low operating costs.

Frequently Asked Questions

- Does VPHP affect ductwork or room finishes?
- How is vapor contained in the target area?
- Cycle duration?
- Differences between an integrated and portable system?
- Enclosure qualification criteria?
- Most common mistakes?
Questions?

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