Implementation of a Change in Cleaning Agent in the Controlled Environment

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Background
United States Pharmacopeia Chapter Pharmaceutical Compounding-Stere Preparations details standards for safety compounding sterile preparations. Requirements include personnel training, cleaning procedures, and environmental monitoring. Direct compounding areas within ISO 5 primary engineering controls must be cleaned before and after compounding, and at least every 30 minutes of continuous compounding. The home infusion organization developed a pilot program to replace a phenol cleaner/disinfectant with a new agent. The new filtered agent would provide a low odor profile, reduce surface contact time and residue, and decrease cleaning time. The organization anticipated a decrease in solution volume usage. After the pilot, the new agent was later rolled out to the entire organization.

Purpose
To determine the impact of changing disinfectant/cleaner on cleaning experiences and efficiency in the controlled environment.

Methods
This descriptive study surveyed compounding staff across the home infusion organization after all sites were converted to the new solution. Respondents were surveyed about application, odor profile, residue, time-saved, and usage before and after solution replacement. Information collected included data from the three pilot locations. Environmental monitoring trends were examined prior to and following the change. Time study methodology was used to determine impact on efficiency. Locations maintained a log to document time to clean, number of employees involved, and the daily amount of solution.

Results
Fifty-three survey responses were received. Forty respondents (77%) stated that the new solution eased their cleaning experience, with an average rating of 3.79 on a scale of 1 to 5. Fifteen (28%) saw rust and discoloration on stainless steel (Figure 2). Environmental monitoring trends were examined prior to and following the change. Time study methodology was used to determine impact on efficiency. Locations maintained a log to document time to clean, number of employees involved, and the daily amount of solution.

Discussion
Data from the pilot indicated minimal odor and residue compared to the previous agent, 67% reduction in solution used, and less time cleaning. Prior to the pilot, locations dedicated 51.8 to 82.5 minutes for cleaning, versus 34.7 to 48.8 minutes with the new solution. The goal was to compare the pilot results to the remainder of the locations. Respondents were also asked comparable questions to pilot locations. Results from this study reproduced pilot study findings.

Conclusion
The results demonstrated that there were fewer odor profile experiences, minimal rust or discoloration, reduced disinfectant/cleaner solution used, and less time dedicated to cleaning the pharmacy cleanroom area.

Table 1: Overall Rating of Disinfectant/Cleaner Solution

<table>
<thead>
<tr>
<th>Overall Rating</th>
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<tbody>
<tr>
<td>1 = Inferior</td>
<td>13</td>
</tr>
<tr>
<td>2 = Standard</td>
<td>20</td>
</tr>
<tr>
<td>3 = Superior</td>
<td>13</td>
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</tbody>
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References
2. USP General Chapter <797—A guide to sterile compounding for pharmacy personnel. https://www.powerpak.com/course/content/114850 (accessed 2021 7 Sep)

Disclosures
Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Camille Moore, Mike Carroll, Glen Gard, Fred Massoomi, Jerry Bliss, Maria Giannakos. Nothing to disclose.

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