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Implementation of a Change in Cleaning Agent in the Controlled Environment

Camille Moore, PharmD; Mike Carroll, BSPharm, RPh, BCSCP; Glen Gard, CPhT-Adv, CSPT; Fred Massoomi, PharmD, BCSCP; Jerry Bliss, RPh, PharmD; Maria Giannakos, PharmD, MBA, BCPS, BCSCP

Option Care Health - Newark, DE

Background

United States Pharmacopoeia Chapter Pharmaceutical Compounding-Sterile Preparations details standards for safely compounding sterile preparations.[1] 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.[1,2]

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.[3] 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 *(Figure 1)*. Thirteen (24%) noticed residue and seven (13%) rinsed the floor after application. Average rating for the odor profile was 3.49 on a scale of odorless (1) to unpleasant odor (5) *(Figure 2)*.

Fifteen (28%) saw rust and discoloration on stainless steel *(Table 1)*. Twenty-nine (55%) used less solution than previously *(Figure 3)*. Thirty-three (62%) reported less cleaning time. During the conversion, nine (17%) had growth between days one and ten. The new solution was rated at 2.28 overall on a scale of 1-3, with 1 as inferior, 2 as neutral, and 3 as superior *(Figure 4)*.

Figure 1:

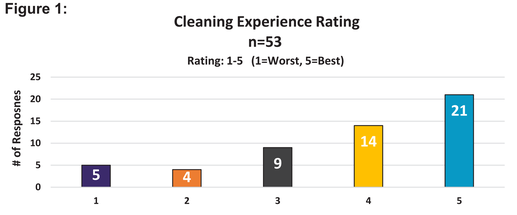


Figure 2:

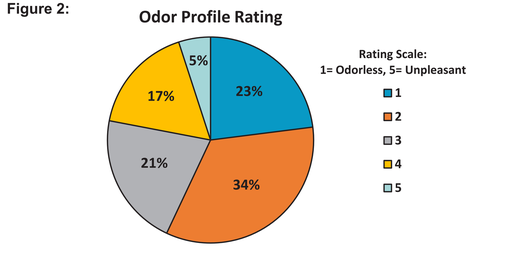


Table 1:

Survey Questions	Yes	No
Unpleasant Odor Profile	18	35
Odor Profile in Cleanroom Areas	14	39
Residue Buildup on Pharmacy Cleanroom Floors	13	39
Rinsing Pharmacy Cleanroom Floors	7	46
Discoloration on Rust or Stainless Steel	15	37
Decreased Dedicated Time Cleaning	33	10
Microbacterial Growth	9	44

Figure 3:

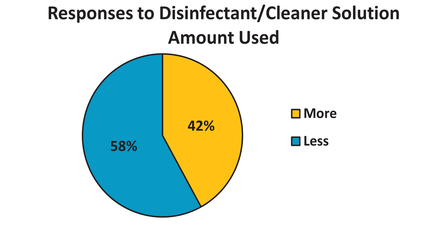
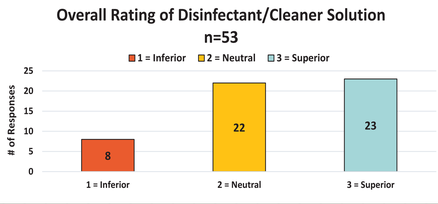


Figure 4:



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 asked comparable questions to pilot locations. Results from this study reproduced the pilot study findings.

This study collected information directly from compounding personnel. Further strengths included the number of responses received and use of ordinal data to determine the odor profile, cleaning experience, and overall rating of the solution. A weakness of this study was the inability to assess open-ended questions for more detailed responses.

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.

The transition away from a phenol cleaner/disinfectant solution to a quaternary ammonium cleaner/disinfectant solution benefited compounding personnel and reduced cleaning time.

References

[1] United States Pharmacopoeia. USP general chapter <797> pharmaceutical compounding—sterile preparations. Rockville, MD: United States Pharmacopoeia; 2008 May.

[2] USP General Chapter <797>: a guide to sterile compounding for pharmacy personnel. https://www.powerpak.com/course/content/114850 (accessed 2021 7 Sep)

[3] Contec Healthcare. TB-1330 Disinfectant Solution. https://www.contechealthcare.com/products/contec-healthcare-tb1-3300-disinfectant/ (accessed 2021 7 Sept)

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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