Reduce cost by reducing frequency of submitting to identify microorganisms isolated from non-critical areas in a parenteral manufacture

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Abstract

The Microbiology laboratory identifies all the microorganisms isolated from the non-critical rooms with a frequency of every three months, with the purpose of establishing a microbial profile of the microorganism present in the areas. The purpose of the project is to reduce 50% of costs by decreasing the identification frequency to biannual. Identifying each microorganism using the MicroSEQ has a cost of $86.18. The data from March, June, September, and December 2019 were evaluated. The data identified 305 microorganisms, which represented a cost to the laboratory of $26,284.90. The microorganisms that predominated in those months were, *Micrococcus luteus*, *Staphylococcus epidermidis*, *Staphylococcus capitis*, *Staphylococcus haemolyticus*, *and Staphylococcus hominis.* By obtaining similar microorganisms in each month, a reduction in frequency, every six months instead of every three months, can be recommended without damaging the microbial profile of the manufacturing areas. The reduction of these annual expenses can give more visibility to the laboratory as well as more competitiveness for new projects.

Key Terms - Environmental Monitoring, Manufacturing rooms, Microbiology and Reduce Cost

Introduction

The microbiology environmental monitoring is the collection of data of microorganisms present in a cleanroom. All microorganisms isolated from Grade A and B areas will have a full identification by genus and species. For microorganisms isolated from the non-critical area, (Grade C and D) full identification is not required, except when alert and action levels are exceeded. It only requires gram and spore stain methods. In addition, the microorganisms isolated from non-critical areas are submitted for full identification every three months (quarterly frequency) with the purpose of establishing a microbial profile of the microorganism present in the areas.
The laboratory uses the MicroSEQ Microbial Identification System to identify all microorganisms that require full identification. This system is a microbial identification tool for bacterial and fungi. It uses genetic information from an unknown organism to compare against a validated library.

Problem

The microbiology laboratory evaluates the identification of the microorganisms isolated from non-critical areas every three months (March, June, September, and December). In this way, the laboratory has data on the microflora of the different areas. The laboratory uses the MicroSEQ Microbial Identification System to classify all microorganisms that require full identification. Currently, the total cost of identifying each microorganism represents approximately $86.18. This total cost represents $35.61 in resources and $50.57 in materials. In 2019, the laboratory submitted for identification, approximately 305 microorganisms isolated from non-critical areas during March, June, September, and December. This action represented $26,284.90 of the annual expenses. High expenses in the laboratory reduce visibility and competitiveness when compared to other manufacturing plants of the company.

Methodology

The project will consist of evaluating data of full identification of microorganisms isolated from non-critical areas. The period of the evaluation consists of March, June, September, and December of 2019. The microorganisms' data from environmental monitoring of rooms where less critical tasks are performed, and where fewer stages from the manufacturing process occurred will be collected. Particularly, the data is documented in the original controlled forms of the manufacturing process. Some examples of these rooms included storage rooms, hallways, equipment wash, clean preparation, material entrance, and exit. A spreadsheet from MS Excel will be used as a tool for data entry, tables, and graphs. To have a successful project, several metrics must be evaluated. For example, metrics such as environmental monitoring evaluation, determinate microorganism's isolation frequency, and the most common type of microorganisms recovered from non-critical areas are vital in this research.

Results and Discussion

There were performed a total of 305 full microbiology identification ID during every three months frequency in 2019. This represents approximately $26,284.90 cost to the laboratory in a year. Refer to Table 1 that summaries all full ID count and cost during March, June, September, and December in 2019. There is no variability of Full ID count and costs each month.

Table 1

Summary of full ID count and costs per months during 2019

Months	Full ID Count	Costs
March	81	$ 6,980.58
June	71	$ 6,118.78
September	77	$ 6,635.86
December	76	$ 6,549.68
Grand Total	**305**	**$26,284.90**

The most frequently isolated microorganisms in 2019 are Micrococcus luteus (23.28%), Staphylococcus epidermidis (18.69%), Staphylococcus capitis (10.82%), Staphylococcus haemolyticus (9.51%) and Staphylococcus hominis (8.85%). These five microorganisms recovered are associated with human born microorganisms and represent 71.15% of all microorganisms isolated from the months evaluated.

Figure 1: Summary of microorganisms isolated in March, June, September and December during 2019

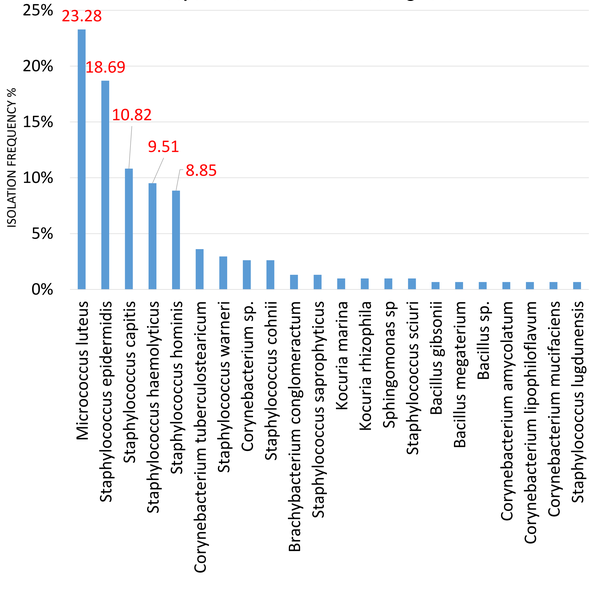


Figure 2: Isolation Frequency % of microorganisms in March 2019

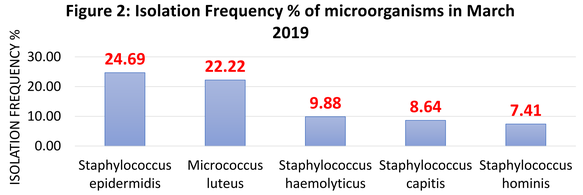


Figure 3: Isolation Frequency % of microorganisms in June 2019

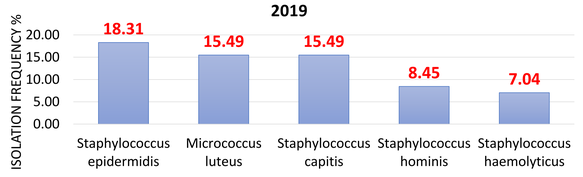


Figure 4: Isolation Frequency % of microorganisms in September 2019

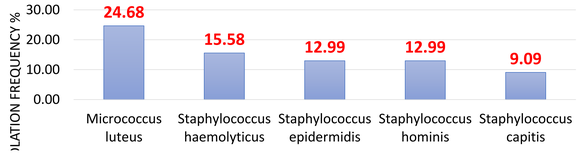
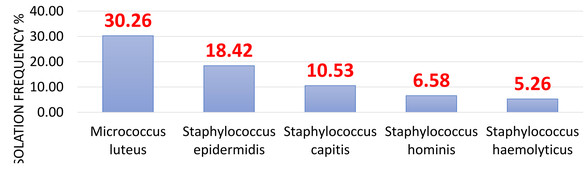


Figure 5: Isolation Frequency % of microorganisms in December 2019



Evaluating each month (Figures 2, 3, 4, and 5) the predominant microorganisms are the same five that are obtained in the summary of microorganism isolated in 2019. These five common microorganisms are *Micrococcus luteus*, *Staphylococcus epidermidis*, *Staphylococcus capitis*, *Staphylococcus haemolyticus*, and *Staphylococcus hominis.* The frequency of these isolated microorganisms represents 72.84% in March, 64.78% in June, 75.33% in September, and 71.05% in December.

Conclusions

This project attempted to evaluate whether it is feasible to reduce the frequency of the identification of microorganisms isolated from non-critical rooms. After evaluating the data of the microorganism isolated every three months, it is recommended to reduce the identification frequency because it was shown that the same common microorganisms are obtained each month. By reducing the frequency from every three months to the biannual basis, the microbiology laboratory can collect important data and establish a microbial profile of microorganisms present in the areas. By implementing the biannual frequency, the microbiology laboratory will reduce 50% of its expenses in materials and resources required to identify microorganisms using the MicroSEQ Rapid Microbial Identification System. To implement this new frequency a training for the employees as well as proper documentation in the laboratory procedures are required.

Future Work

Evaluate material costs of other equipment and methods that can be used to identify microorganisms. For example, make a cost-benefit comparison between MicroSEQ and Maldi-tof equipments.

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