Reduction of the Excessive Use of RODAC and STA Plates in Pharmaceutical Industries

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Abstract — *This project aims to solve the problem of the pharmaceutical companies' excessive use of RODAC and STA plates, which increases waste production and negatively affects the environment. The study uses a thorough methodology that combines qualitative and quantitative research to find the causes of these plates' excessive use and suggests waste reduction techniques. The technique consists of data gathering to estimate plate usage and related expenses, interviews to understand the current usage, and a literature review to investigate current practices. The results will be used to modify and intervene in pharmaceutical manufacturing processes to minimize plate usage and increase efficiency and sustainability. This initiative aims to promote eco-friendly methods in the pharmaceutical sector, which will enhance resource management and lessen environmental impact.*

Key Terms — *Continuous Improvement, Process Optimization, Sustainability, Waste Reduction.*

PROBLEM STATEMENT

The excessive use of RODAC and STA plates has emerged as a significant challenge in pharmaceutical industries, leading to increased waste generation, environmental impact, and operational inefficiencies. Despite these plates' critical role in ensuring product quality and safety, their overuse has raised concerns regarding resource utilization and sustainability. The use of RODAC and STA plates beyond necessary levels contributes to unnecessary costs, strains environmental resources, and undermines efforts toward greener manufacturing practices. This issue requires attention to identify the root causes of excessive plate usage, evaluate the associated costs and environmental consequences, and develop targeted strategies for waste reduction while maintaining quality assurance standards within pharmaceutical manufacturing processes.

RESEARCH DESCRIPTION

The excessive use of Settle Plates (STA) in pharmaceutical industries, where multiple plate packages are opened but only a fraction of them are utilized, poses several challenges and inefficiencies. This practice results in unnecessary waste of resources, including materials, labor, and disposal costs. Specifically, when ten STA plate packages are opened but only one of them is used, it leads to significant overconsumption and environmental impact without corresponding benefits in microbial monitoring.

This problem not only increases operational costs but also contributes to environmental pollution associated with manufacturing, transportation, and disposal of unused agar plates. Additionally, the indiscriminate opening of multiple plate packages can compromise the sterility and shelf-life of the remaining plates, potentially affecting the accuracy and reliability of subsequent monitoring efforts.

The inefficient use of STA plate packages highlights the need for a more sustainable and cost-effective approach to environmental monitoring in pharmaceutical settings. Addressing this issue requires implementing strategies to optimize plate usage, minimize waste, and improve resource efficiency while maintaining stringent quality standards and regulatory compliance. By tackling this problem, pharmaceutical companies can enhance operational efficiency, reduce environmental impact, and promote responsible stewardship of resources in their manufacturing processes.

RESEARCH OBJECTIVES

Research objectives are specific, clearly defined goals that guide a research project. They describe what the researcher aims to achieve by conducting the study and outline the steps or milestones necessary to reach these goals. Research objectives help ensure that the research is focused, relevant, and provides useful results. They typically align with the broader research question or problem statement and serve as a roadmap for the entire research process. The objective of the project is to implement strategies aimed at optimizing plate usage, reducing resource consumption, enhancing environmental sustainability, and improving cost-efficiency within pharmaceutical manufacturing processes while maintaining high standards of microbial

Optimize Agar Plate Usage

Optimizing agar plate usage refers to maximizing the efficiency and effectiveness of agar plates in microbiological experiments or laboratory settings. Agar plates are commonly used for growing and isolating microorganisms, including bacteria and fungi. A way to optimize this usage is:

- Implementing strategies to minimize the number of STA and RODAC plates used per monitoring event while ensuring effective detection and quantification of microbial contamination.

Reduce Resource Consumption

Reducing resource consumption refers to strategies and practices aimed at minimizing the use of natural resources in various activities, such as production, consumption, and waste generation. This approach is essential for environmental sustainability, as it helps conserve ecosystems, reduces pollution, and lowers greenhouse gas emissions. this can be achieved by:

- Quantifying the current resource consumption associated with STA and RODAC agar plates, including materials, labor, and disposal costs.

Enhance Environmental Sustainability

Enhancing environmental sustainability involves practices and policies aimed at minimizing negative impacts on the environment and promoting the health of ecosystems. It focuses on balancing economic development, social equity, and environmental protection. Some ways this can be achieved are:

- Understand the environmental impact of current agar plate usage, including energy consumption, waste generation, and carbon footprint.
- Develop strategies to enhance environmental sustainability by reducing waste generation, optimizing supply chain logistics, and adopting eco-friendly practices in environmental monitoring.

Promote Cost Savings and Operational Efficiency

Promoting cost savings and operational efficiency involves implementing strategies and practices aimed at reducing expenses while maximizing productivity and resource utilization within an organization. This approach is essential for improving profitability, competitiveness, and overall performance. To achieve this, we must:

- Quantify the potential cost savings associated with reducing STA and RODAC agar plate usage through improved efficiency and resource optimization.
- Develop a business case highlighting the economic benefits of using individual plate packages to reduce operational costs and enhance overall efficiency.

This objectives can give us the key elements needed to be able to avoid extra costs and waste generations in pharmaceutical industries.

RESEARCH CONTRIBUTIONS

The main contribution will be finding a better alternative for STA and RODAC plate packages that will accommodate our needs and help reduce cost from biohazard waste pickup and material cost reduction.

LITERATURE REVIEW

Environmental monitoring is a tool to assess environmental conditions and trends, support policy development and its implementation, and develop information for reporting to national policymakers, international forums, and the public [1]. In pharmaceutical manufacturing facilities, environmental monitoring plays a critical role in ensuring the safety and quality of products [2]. Surface and air monitoring are commonly performed using agar plates such as Settle Plates (STA) and RODAC (Replicate Organism Detection and Counting) plates to detect microbial contamination. However, the excessive use of these agar plates can result in increased costs, resource consumption, and environmental impact. Therefore, this project aims to explore strategies for optimizing the use of STA and RODAC agar plates in pharmaceutical industries, with the goal of reducing waste while maintaining stringent quality standards.

Environmental monitoring is essential in pharmaceutical facilities to comply with regulatory requirements and prevent contamination risks. The frequent and widespread use of these agar plates can lead to significant resource consumption, including materials, labor, and disposal costs. Additionally, the production and disposal of agar plates contribute to environmental impacts, such as energy use and waste generation. This project will focus on developing strategies to streamline environmental monitoring procedures, reduce the number of agar plates used, and implement alternative monitoring methods where feasible.

By addressing these issues, pharmaceutical companies can achieve cost savings, minimize environmental footprint, and enhance overall efficiency in their manufacturing processes. Ultimately, the project aims to demonstrate that reducing STA and RODAC agar plate usage can lead to sustainable improvements in pharmaceutical manufacturing, aligning with industry trends towards greater efficiency. The way we aim to do so is by optimizing the agar plate usage, reducing the resource consumption, enhancing environmental sustainability, promoting cost savings and operational efficiency. This problem not only increases operational costs but also contributes to environmental pollution associated with manufacturing, transportation, and disposal of unused agar plates. Additionally, the indiscriminate opening of multiple plate packages can compromise the sterility and shelf-life of the remaining plates, potentially affecting the accuracy and reliability of subsequent monitoring efforts.

The project was discussed with management to present our efficiency and waste reduction ideas for the inoculation rooms in the manufacturing areas with the purpose of reducing excessive waste and disposal costs. The excessive use of Settle Plates (STA) in pharmaceutical industries, where multiple plate packages are opened but only a fraction of them are utilized, poses several challenges and inefficiencies. This practice results in unnecessary waste of resources, including materials, labor, and disposal costs. Specifically, when ten STA plate packages are opened but only one of them is used, it leads to significant overconsumption and environmental impact without corresponding benefits in microbial monitoring.

METHODOLOGY

The methodology for my project, involves an approach that combines both qualitative and quantitative methods. My approach involves a combination of qualitative and quantitative methods to gain a comprehensive understanding of the issue [3]. Qualitative research methods allow me to explore the underlying reasons and contextual factors influencing the excessive use of RODAC and STA plates. Through qualitative approaches such as interviews, focus groups, and observational studies, I can gather insights into the attitudes, behaviors, and decision-making processes of key stakeholders within pharmaceutical manufacturing facilities. This qualitative data provides rich and detailed information on the challenges, perceptions, and barriers to reducing plate usage, helping to uncover different perspectives and potential solutions.

On the other hand, quantitative research methods play a vital role in quantifying the extent of plate usage and evaluating the effectiveness of reduction strategies. Through quantitative techniques such as surveys, data analysis, and statistical modelling, I can measure the frequency and volume of plate usage, identify patterns and trends over time, and assess the impact of interventions or initiatives aimed at reducing waste. By collecting numerical data on plate consumption, waste generation, and associated costs, I can generate empirical evidence to support decision-making and measure progress towards sustainability goals. Combining qualitative insights with quantitative data allows for a holistic approach to understanding and addressing the issue of excessive plate usage in pharmaceutical industries, enabling informed strategies for waste reduction and process improvement [4].

Here's an outline of the methodology:

Qualitative Research

- Conduct semi-structured interviews with workers involved in pharmaceutical manufacturing, including production managers, quality assurance personnel, and environmental health and safety specialists.
- Explore their perceptions, attitudes, and practices related to RODAC and STA plates usage.
- Gather insights into factors influencing plate selection, usage patterns, challenges, and potential barriers to reducing plate usage.

Quantitative Research

- Collect data on plate usage and waste generation through direct observation, record-keeping, and analysis of production logs.
- Quantify the frequency and volume of RODAC and STA plates used in different stages of the manufacturing process.
- Calculate the associated costs and environmental impact of excessive plate usage.

Data Analysis

- Analyze qualitative data from interviews using thematic analysis to identify recurring themes, patterns, and key findings.
- Analyze quantitative data using statistical methods to identify trends, correlations, and areas for improvement.
- Integrate qualitative and quantitative findings to develop a comprehensive understanding of the factors contributing to excessive plate usage and potential solutions.

Implementation and Evaluation

- Implement initiatives aimed at reducing plate usage, such as process optimizations, technology upgrades, or employee training programs.
- Monitor and evaluate the effectiveness of these interventions using key performance indicators (KPIs) such as plate usage reduction, cost savings, and environmental impact.

By using a mixed-methods approach that combines qualitative and quantitative research methods, the methodology aims to provide a holistic understanding of the problem and facilitate the development of targeted interventions to reduce the excessive use of RODAC and STA plates in pharmaceutical industries.

RESULTS AND DISCUSSION

This project aimed at reducing the excessive use of RODAC (Replicate Organism Detection and Counting) and STA (Surface Testing Agar) plates in pharmaceutical industries yielded significant findings. Through a detailed analysis of the current usage patterns, it was discovered that a big amount of these plates was being utilized unnecessarily due to the packages that were being purchased. Some of the positive results obtained with the implementation on smaller RODAC and STA plate packages were:

- **Reduction in Plate Usage**: After implementing optimized sampling protocols and revising the Standard Operating Procedures (SOPs), there was a reduction in the use of RODAC and STA plates across the manufacturing sites. This reduction not only decreased the cost associated with purchasing these plates but also minimized waste generation.
- **Cost Savings**: The reduction in plate usage translated into significant cost savings for the company. It was calculated that the company saved approximately $100,000 annually by reducing the overuse of these plates.
- **Environmental Impact**: The project also had a positive environmental impact, as the reduced use of RODAC and STA plates led to a decrease in the amount of plastic waste as well as toxic waste generated. This supports the company's sustainability goals and reduces the environmental footprint of the manufacturing processes.

The RODAC and STA plates packages being currently used in the manufacturing area contain 10 plates each from which only 2 RODAC are used and 8 STA plates per process. This produced a high amount of waste because once a package is opened, for aseptic reasons they cannot be reused. After evaluation of different options, we came across plates that came in separate packages and were put to the test in the manufacturing processes as well as STA plates that came in smaller quantities.

In my building there are four shifts in my area of work. This groups are composed of 6 people certified to work in the inoculation room. The experiment ran for 2 months to be able to give all the people the opportunity to participate and see their usage of the plates. The first month was used for the packaged plates and the second month for the plates in individual packages. Each shift group was asked how much plates were wasted by package by person when working on the inoculation process and the following results were obtained.

Figure 1
Data for Group 1

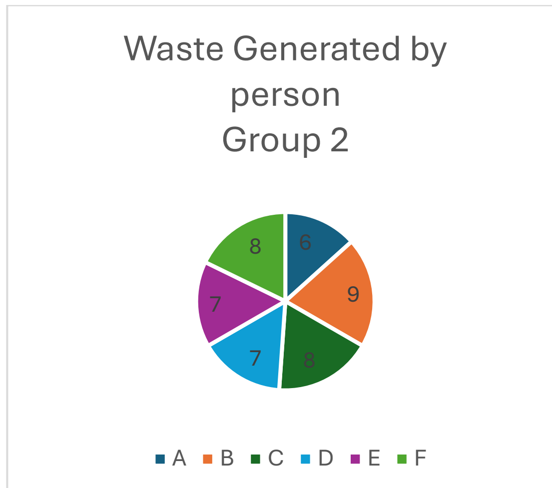

Figure 2
Data for Group 2

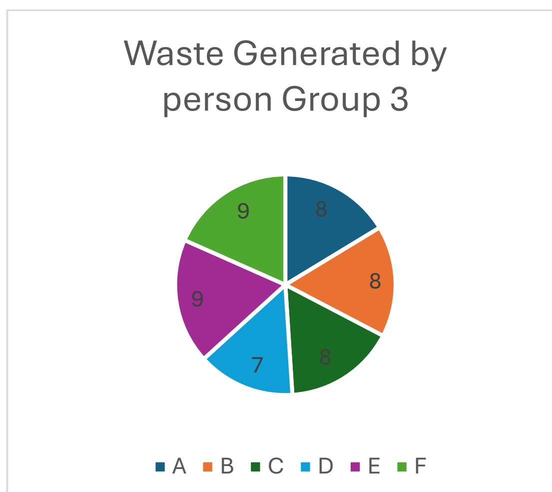

Figure 3
Data for Group 3

Figure 4
Data for Group 4

From the figures above, we can see that from packages containing 10 plates each, every person discarded more than half the package. This id because the process is made to last mostly an hour and a half, and each plate is used for runs of 1 hour at most. The people who use 3 or 4 is because something unusual happens and the process lasts longer but is not the day-to-day process. An average of 8 plates are discarded by person which if we see it day by day having more than one process it ends up in a very high amount of waste generated with this material.

Comparing this data with other areas that use our same materials was essential to be able to change the supplier and be able to get packages that contained a smaller number of plates. Five other teams were used in the survey and the results were as follows:

Figure 5
Data for Area A

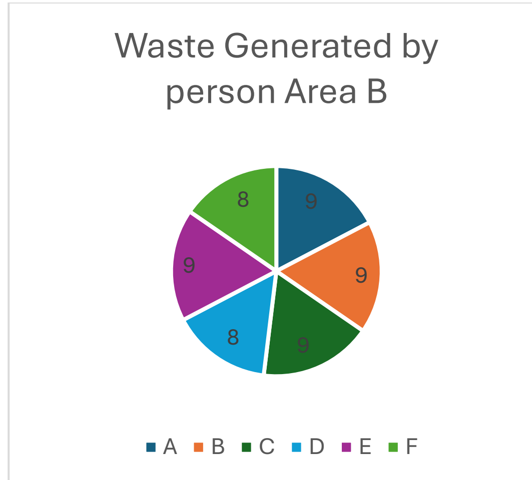

Figure 6
Data for Area B

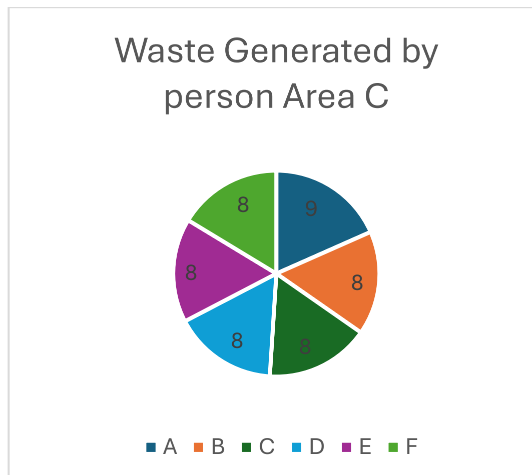

Figure 7
Data for Area C

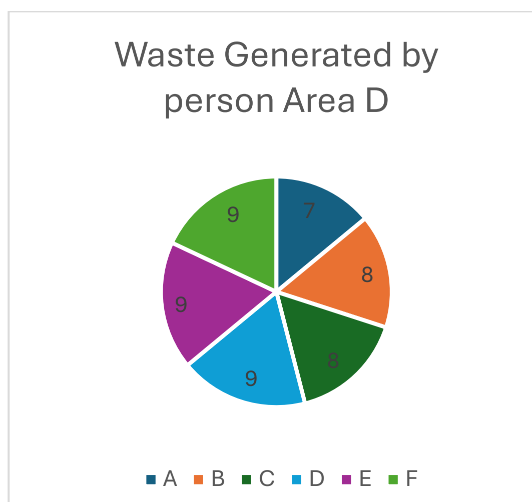

Figure 8
Data for Area D

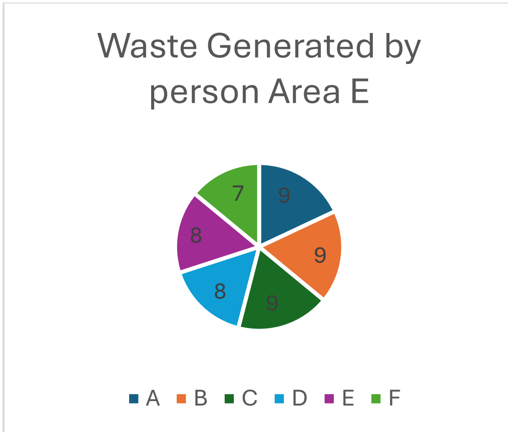

Figure 9
Data for Area E

Analysing the obtained data for the different areas that also use these plates, we can see that they also discard the majority of the plates in the package. They have a higher amount of waste because their processes are shorter therefore, they use less plates than the aseptic areas.

Plates that come in individual packages were proposed to replace the current packages. These plates were purchased and used to verify if it was cost effective for the company, reduced waste generation and if they were effective and non contaminated. This part of the experiment measures the waste generation from individual packages that came with defects. The same 9 groups were used for this experiment. The 4 groups that belong to the manufacturing area in question had a significant result:

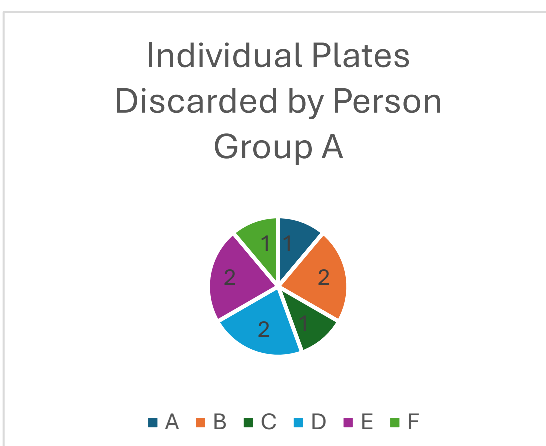

Figure 10
Second Data for Group A

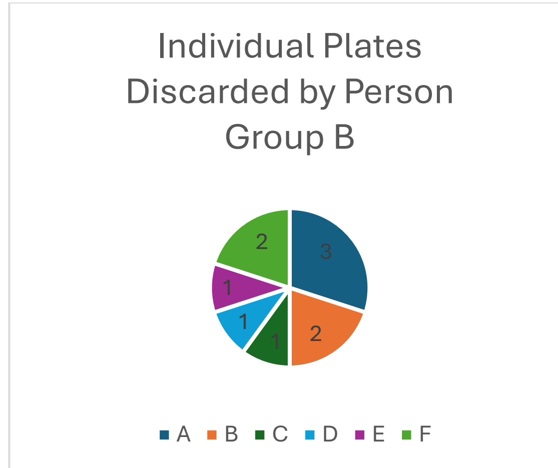

Figure 11
Second Data for Group B

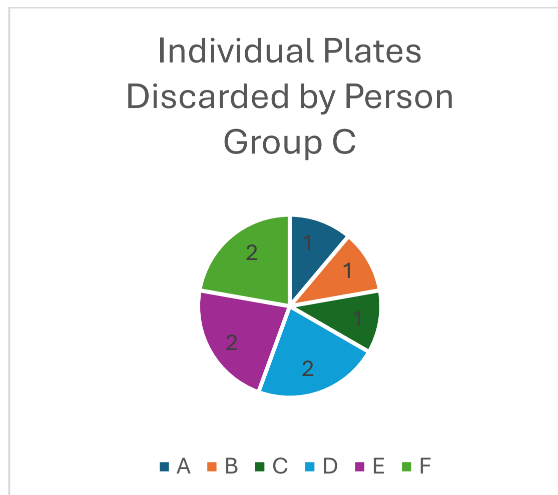

Figure 12
Second Data for Group C

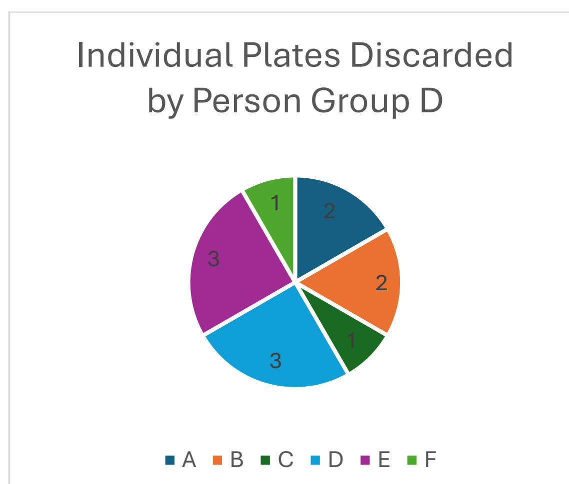

Figure 13
Second Data for Group D

As we can see, overall, 1 to 2 plates were discarded by person due to defects on the plate. This inspection is not something that the worker can control. Plates with defects have always been discarded, but, with this method, it was easier to manage the waste generated by plates that were not defected and that had to be discarded because the package had already been opened. Each person uses their personal criteria to pass or fail the visual inspection of this plates, but a small number of plates were discarded overall. If we compare this numbers with the ones shown in figures 1, 2 3 and 4, we can see that there was a decrease from 8 plates discarded by person to only 2. This reduces the cost of waste management for the company.

The same evaluation was made with the other 5 areas that use this material and the results were as follows:

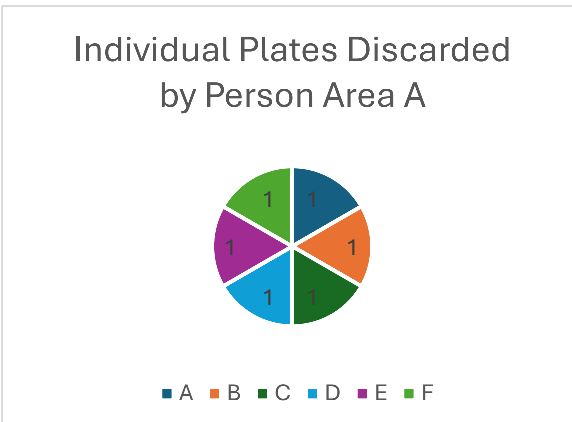

Figure 14
Second Data for Area A

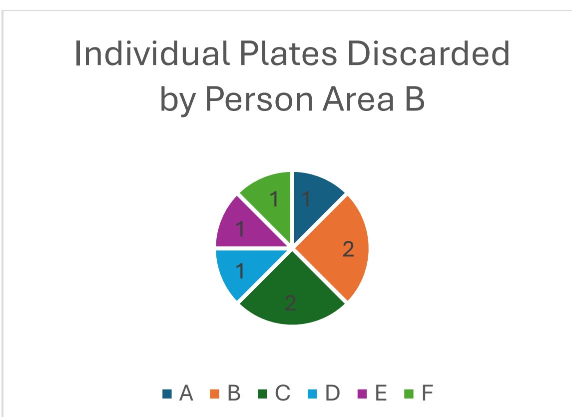

Figure 15
Second Data for Area B

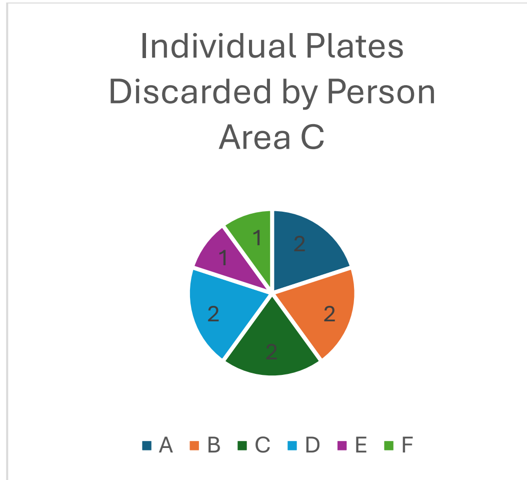

Figure 16
Second Data for Area C

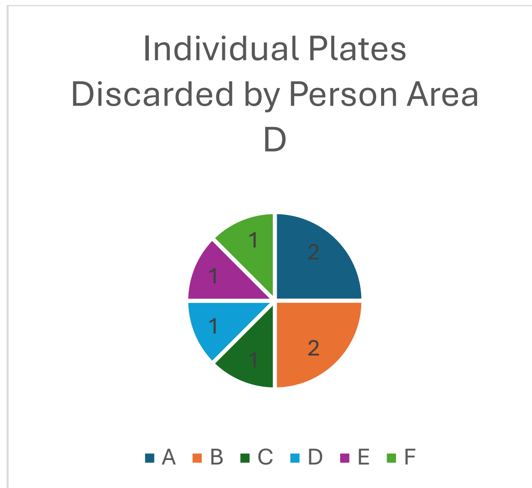

Figure 17
Second Data for Area D

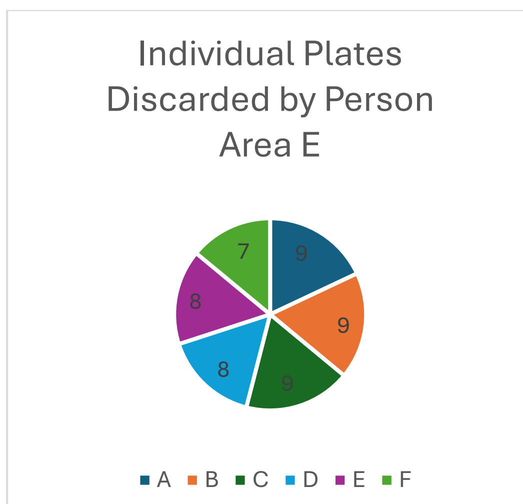

Figure 18
Second Data for Area E

One to two plates were discarded by a person in these areas as well. Below we will see a comparison of the waste generated with the packages containing 10 plates each vs the plates that come in individual packages.

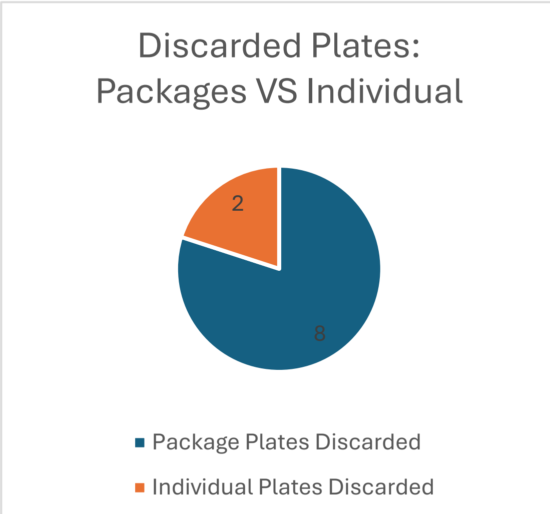

Figure 19

Comparison of Waste Generated from Multiple Packaged Plates and Individual Plates

About an 80% hazardous waste reduction was obtained with this experiment. This helps reduce the cost of hazardous waste management for the company and the individual plates come at a lower cost.

The reduction in the excessive use of RODAC and STA plates highlights the importance of reviewing and optimizing standard practices within the pharmaceutical industry. The results indicate that many companies might be following outdated or overly cautious protocols or making unnecessary expenses with this type of plates. By carefully analyzing and revising the costs of purchase of different plates, significant cost and environmental benefits can be achieved without compromising product quality or safety.

The success of this project also emphasizes the importance of cross-functional collaboration between the quality assurance, microbiology, and manufacturing departments. Through joint efforts, the team was able to identify inefficiencies and implement changes that were both practical and beneficial to the company as a whole.

Furthermore, this project illustrates the value of continuous improvement initiatives in highly regulated industries like pharmaceuticals. Regularly revisiting and assessing the relevance of current practices ensures that companies remain competitive, efficient, and aligned with best practices.

Overall, the project demonstrates that careful evaluation and adjustment of not only standard procedures, but also the materials being used can lead to significant improvements in both cost efficiency and environmental sustainability, while maintaining the stringent quality standards required in the pharmaceutical industry.

Conclusion

This project successfully demonstrated that significant improvements in resource efficiency can be achieved through the optimization of existing practices. By revisiting and refining the sampling protocols, the excessive and unnecessary use of RODAC and STA plates was significantly reduced, leading to substantial cost savings and a decrease in environmental waste.

The initiative not only resulted in a high percent reduction in plate usage but also enhanced the overall efficiency of microbiological testing processes. These changes underscore the importance of continuous improvement and cross-departmental collaboration in driving operational excellence in the pharmaceutical industry. The project highlights that with strategic adjustments, companies can maintain high standards of quality control while also reducing their operational costs and environmental impact.

Moreover, the environmental benefits of this reduction should not be understated. The decrease in plate usage resulted in a tangible reduction in plastic waste, aligning the company's operations with broader sustainability goals. This environmental impact is particularly important in an industry where regulatory demands often result in high levels of consumable waste. By optimizing resource use, the project contributes to the ongoing efforts within the pharmaceutical industry to minimize environmental footprints.

This attempt sets a precedent for ongoing evaluations of standard procedures and encourages the pharmaceutical industry to seek out further opportunities for process optimization. This helps companies achieve not only a sustainable operation, but also a cost-effective one, benefiting both the organization and the community.

The project also underscores the value of cross-functional collaboration. The successful reduction in plate usage was made possible by the collective efforts of the quality assurance, microbiology, and manufacturing teams. This collaborative approach not only facilitated the identification of inefficiencies but also ensured that the implemented changes were practical and widely accepted within the organization.

In conclusion, the project serves as a compelling case study for the potential benefits of process optimization in the pharmaceutical industry. It demonstrates that by challenging established norms and seeking opportunities for improvement, companies can achieve significant cost and environmental benefits while maintaining high standards of product safety and quality. This project should inspire continued efforts in the pharmaceutical sector to explore similar initiatives that promote sustainability, efficiency, and innovation. As the industry continues to evolve, the lessons learned from this project will be invaluable in guiding future improvements and ensuring that operational practices remain both effective and environmentally responsible.

REFERENCES

[1] HSE Masters. (2018). *Environmental Services* [Online]. Available: http://www.hsemastersltd.com/environmental-services/

[2] Asis Europe. (n. d.). *Dr Finn Morgan* [Online]. Available: https://asiseurope.org/meet-our-speakers/dr-finn-morgan/.

[3] Howuku Blog. (2023). *User Journey Testing Guide* [Online]. Available: https://howuku.com/blog/user-journey-testing.

[4] Sydney Aboriginal Family Support Service (SAFSS). (2018). *Winangay Carer Assessments | SAFSS* [Online]. Available: https://www.safss.com.au/general-1-2.