

Process Optimization of Humidification Step for Powdered Raw Material



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Abstract

This study investigates the optimization of the humidification process for Raw Material A (RMA) in a medical device manufacturing facility. The humidification process, essential for preparing RMA for subsequent manufacturing steps, was analyzed using the DMAIC methodology. The humidification step was identified as the bottleneck in the manufacturing process. Analyzing temperature and humidity records revealed that adjusting the humidity control loop could expedite the process. Feasibility studies confirm that increasing the loop rate value significantly reduces setup time and cycle duration while allowing for a larger batch size. Results indicate a 90% reduction in setup time, a 24% reduction in cycle time, and a 40% increase in batch size. These findings suggest considerable improvements in efficiency and productivity, preparing the facility to meet future demand increases. Recommendations for implementation are made, anticipating enhanced manufacturing capabilities by the end of 2024.

Introduction

In a medical device manufacturing facility, powdered Raw Material A (RMA) undergoes a humidification process to prepare it for the next manufacturing step. This process is used in industries that handle powdered raw materials in which moisture is added to the material to achieve specific properties. The main equipment used for this is a humidity chamber, also known as an environmental chamber.

Much like a home refrigerator appliance, this equipment is used to subject the RMA to specific temperature and humidity conditions. In this case, with the sole purpose of increasing the moisture content of the raw material. The RMA is humidified using a validated system profile that contains a set of parameters that help control the temperature and humidity inside the chamber to achieve the moisture content required for the material.

A single batch of RMA takes a minimum of 13.5 hours from start to finish and is currently considered the bottleneck step of the whole manufacturing process. As product demand keeps increasing, the desire is to optimize the humidification process by reducing its cycle time for each batch while also increasing the batch size has grown within the company.

Methodology

The DMAIC methodology was used to address the opportunities found in the manufacturing facility. It is a data-driven Six Sigma strategy used to improve processes [1]. DMAIC stands for Define, Measure, Analyze, Improve, and Control which are the phases that make up the methodology. The Define and Measure phases were performed in parallel by evaluating the time consumed by each step of the end-to-end manufacturing process. This resulted in a Pareto chart in which the humidification step was shown to be the most time-consuming. A single batch of RMA takes a minimum of 13.5 hours from start to finish and is currently considered the bottleneck step of the whole manufacturing process. The current process for RMA is divided into three activities, as shown in Figure 1.

The equipment setup consists of preparing the equipment by setting the desired temperature and humidity parameters in which the material will be processed and letting the chamber reach each setpoint for approximately 2.5 hours. This is also called the pre-conditioning and after it is completed, the RMA is then introduced into the chamber and a predetermined system profile is started. This step takes up to a minimum of 10.5 hours.

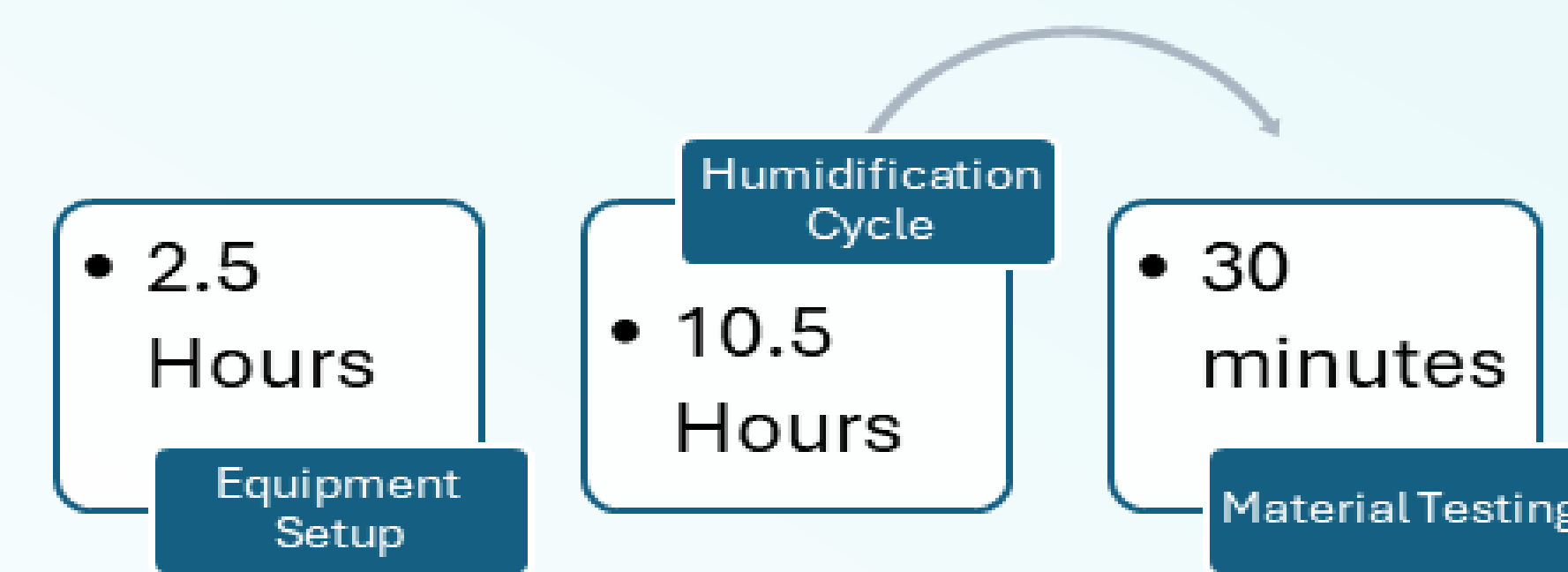


Figure 1. Humidification Process for RMA

The final activity takes approximately 30 minutes to complete and consists of removing the material and testing it to confirm it reached the desired moisture content. Given that the testing activity was the least time-consuming of the three, it was left out of the scope of the project.

During the Analyze phase, the temperature and humidity records for multiple batches were evaluated. This showed that the equipment reached its temperature setpoint faster than it reached its humidity setpoint. Therefore, the equipment parameter values were evaluated to determine if a Proportional-Integral-Derivative (PID) controller tuning was likely to help improve the cycle. It was found that the temperature and humidity of the humidity chamber were controlled by two loops.

A control loop consists of sensors to measure temperature or humidity, controller hardware, and actuators that communicate with each other to reach or maintain the equipment on or near the setpoint [2]. A general control loop block diagram is shown in Figure 2. The sensor sends the controller the parameter value which it interprets and generates a signal to the actuators.

For the humidity chamber, Control Loop 1 controls the temperature while Control Loop 2 controls the humidity inside the equipment.

Given the opportunity to reduce the cycle time laid by reducing the time the chamber reached the humidity setpoint, Control Loop 2 was determined to be the one that required adjustment which was addressed as part of the Improve phase. A feasibility study was performed to put new Control Loop 2 parameters to the test.

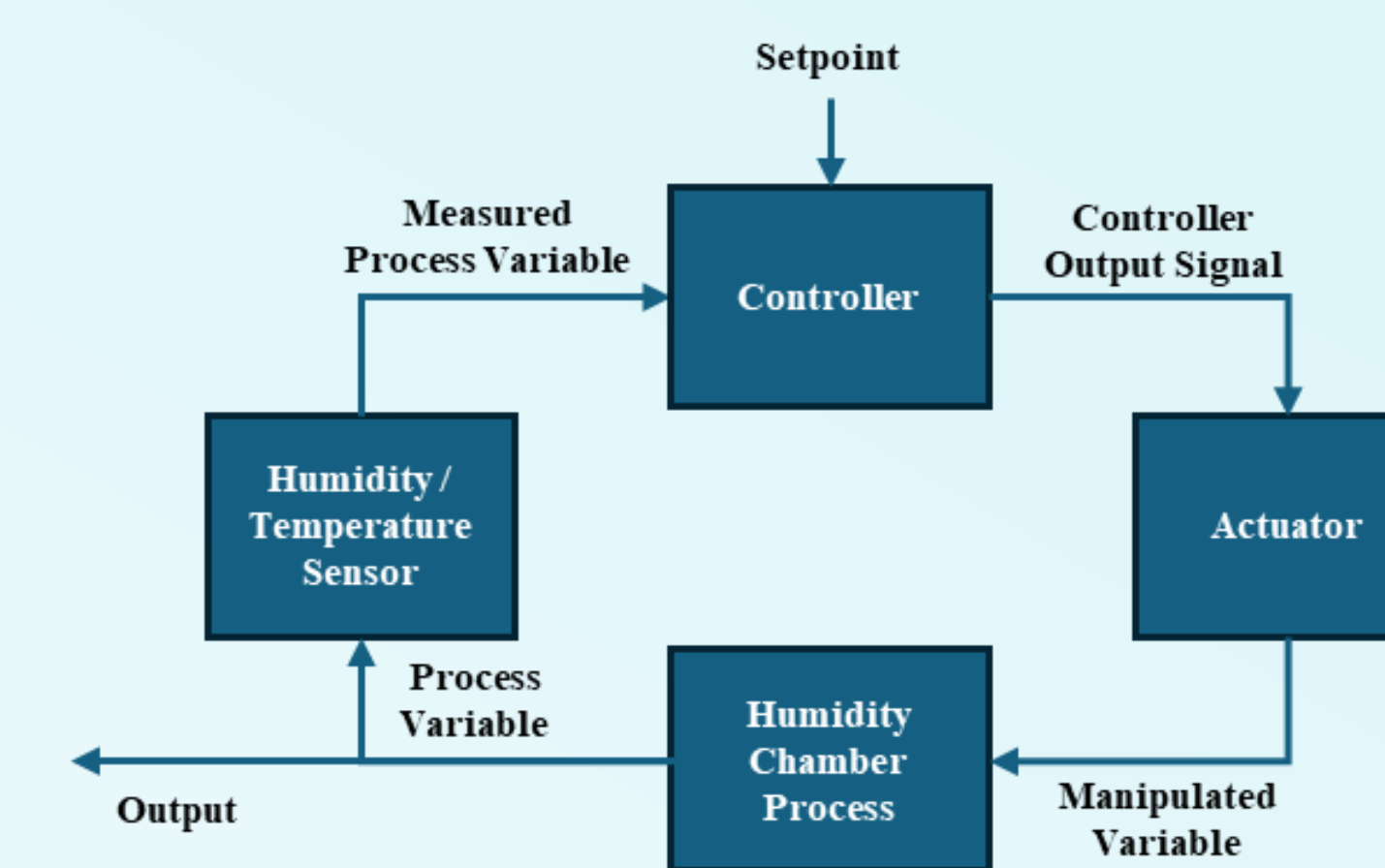


Figure 2. General Control Loop Diagram

The idea was to increase the Control Loop 2 rate value from less than 1.0 to greater than 20.0 to help reach the humidity target setpoint of 90% faster during the humidification cycle. The batch size was nearly doubled during these tests to study if this new parameter value had any impact on a bigger batch. Currently, a total of eighteen (18) trays are filled with the RMA (Figure 3) and the proposed configuration was to increase that to thirty (30) trays per cycle (Figure 4).

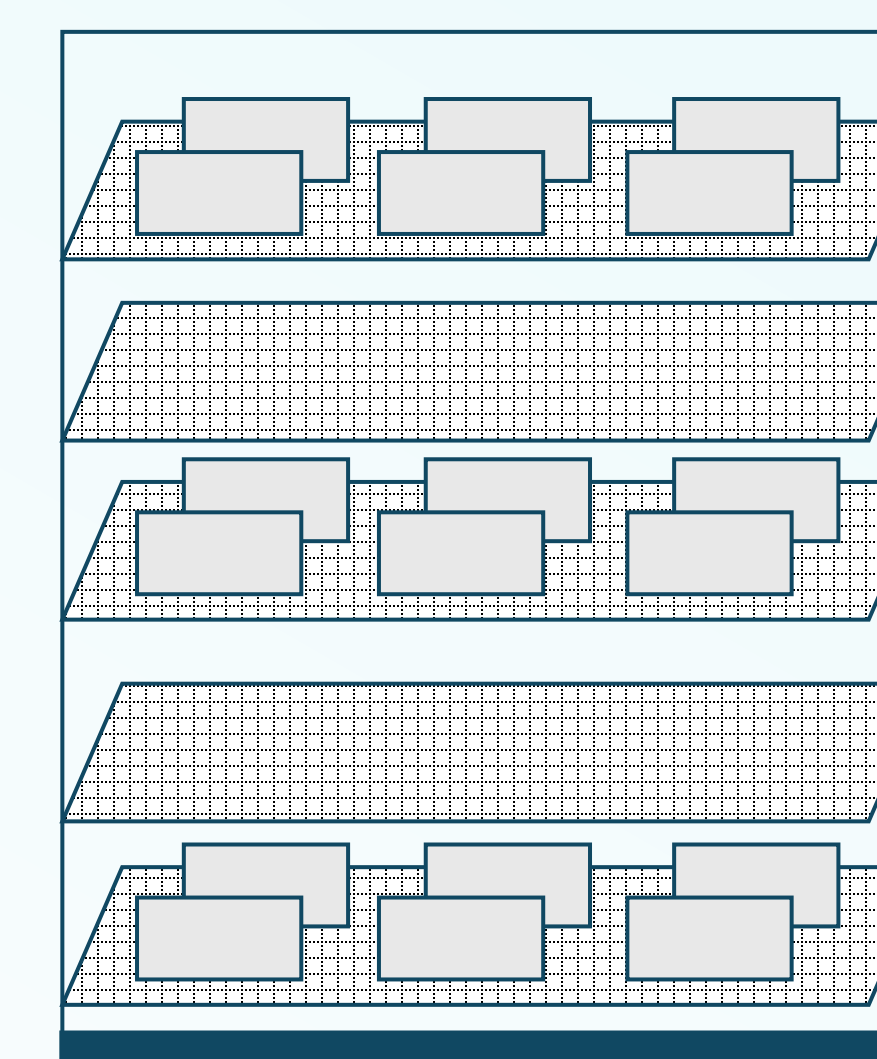


Figure 3. Current Chamber Configuration

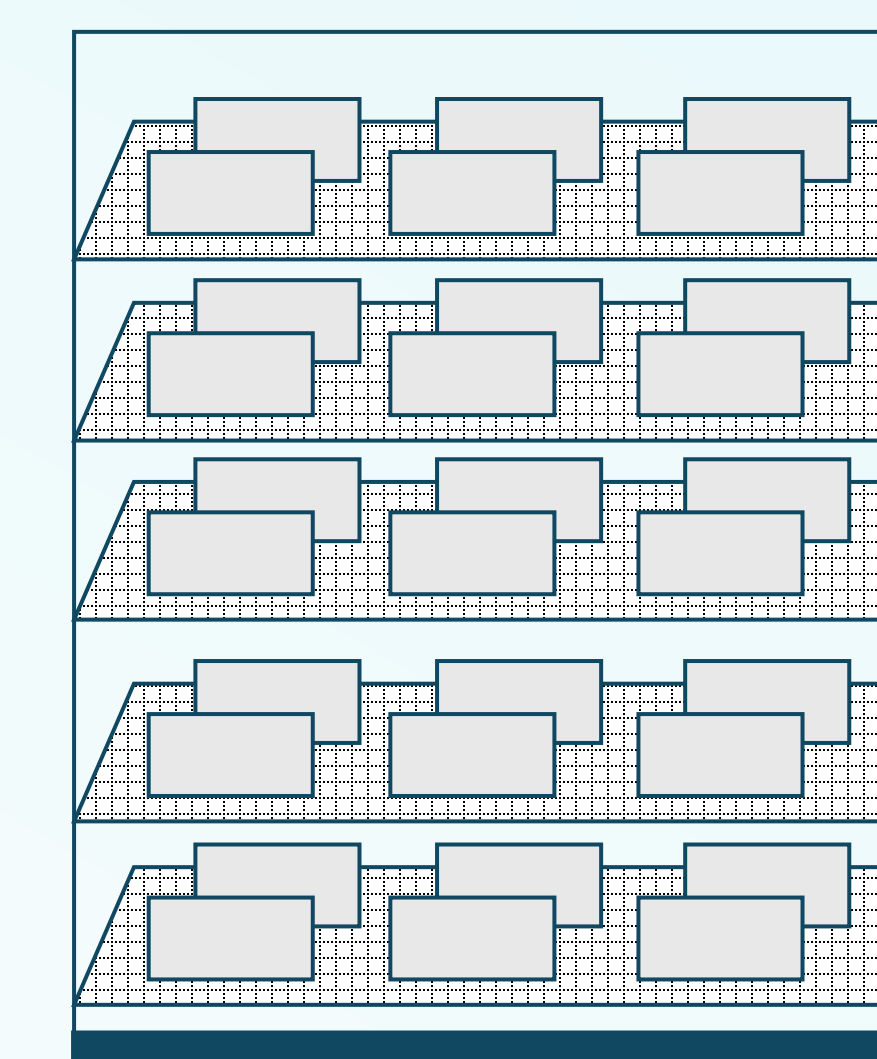


Figure 4. Proposed Chamber Configuration

Results

The chart record for the first batch showed that the equipment reached the humidity setpoint in approximately 10 minutes, which was faster than expected. The moisture content of the RMA reached its target at approximately the eighth hour of the process.

Table 1 shows the feasibility study results and how they compared to the current process. The feasibility study resulted in the following improvements:

- Equipment setup time reduced by 90%.
- Profile cycle time reduced by 24%.
- Batch size increased by 40%.

Table 1. Comparison Between Current and Proposed Change

Parameter	Current Process	Proposed Process
Setup Time	150 minutes	15 minutes
Humidity Loop Rate	< 1.0	> 20.0
Profile Cycle Time	10.5 hours	8 hours
Number of Trays	18	30

The feasibility study had results that could translate to significant improvement in the long run. A Control phase could not be completed given that the project's scope was to find alternatives to improve the current cycle.

Conclusion

After the evaluation and the feasibility study performed, the project was able to obtain positive results. These findings will be key to optimizing the humidification cycle to meet any increased product demand projected in the future. These recommendations were shared with the manufacturing staff for improvement strategy implementation to begin by the end of 2024.

References

- [1] American Society for Quality, "DMAIC process: Define, measure, analyze, improve, control," ASQ, 2019. <https://asq.org/quality-resources/dmaic>
- [2] K. Stouffer, "Guide to Operational Technology (OT) Security," Jan. 2023, doi: <https://doi.org/10.6028/nist.sp.800-82r3>.