Optimization of Water Consumption in HV100 Extraction and Hydration Process

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Abstract

Water consumption in high-volume manufacturing environments represents a significant operational and sustainability challenge, particularly in rinse-intensive processes requiring continuous deionized (DI) water flow. Within the High Volume 100 (HV100) business unit, the Extraction and Hydration (E&H) process was identified as a major contributor to overall plant water consumption. This study evaluated a process optimization strategy to reduce DI water flow from 10 L/min to 5 L/min using a Lean Six Sigma DMAIC methodology. Engineering Study (ES), Operational Qualification (OQ), and Performance Qualification (PQ) activities were executed under worst-case and normal manufacturing conditions to verify that the proposed reduction maintained acceptable process performance and product quality. Results demonstrated that evaluated parameters remained within established acceptance criteria, while the proposed optimization is expected to reduce annual DI water consumption by approximately 50%, from nearly 34 million gallons to approximately 17 million gallons annually.

Introduction

In silicone contact lens manufacturing, the Extraction and Hydration (E&H) process within the High Volume 100 (HV100) business unit consumes significant amounts of deionized (DI) water due to the continuous rinse flow required during production. Increasing production demand and sustainability initiatives created the need to reduce water consumption without affecting product quality. This project evaluated the reduction of DI water flow from 10 L/min to 5 L/min using a Lean Six Sigma DMAIC methodology within a regulated manufacturing environment.

The validated E&H process uses a constant 10 L/min water flow in Tanks 6, 7, and 8 to rinse lenses after Industrial Denatured Alcohol (IDA) extraction and before machine exit. The objective of this project was to confirm that reducing the water flow to 5 L/min would not impact product specifications or validated process performance. Figure 1 presents the current HV100 process flow and rinse configuration.

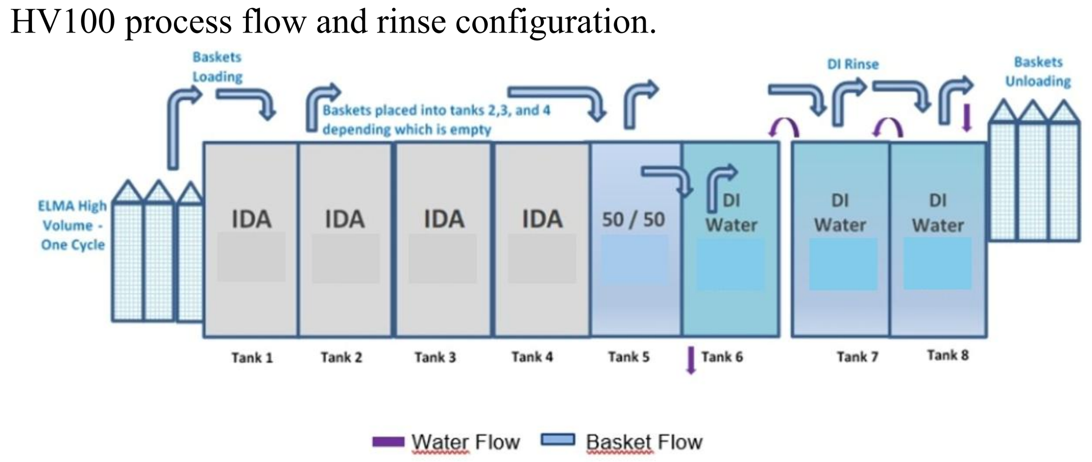

Figure 1. Extraction & Hydration Process Overview

The E&H process consumes approximately 34 million gallons of USP/DI water annually at an estimated cost of $500K. This project aims to reduce water consumption by 50%, generating estimated annual savings of approximately $250K while maintaining validated product performance.

Literature Review

Water consumption in manufacturing processes is closely associated with production demand, process design, and operational efficiency. Lean Six Sigma methodologies, particularly the DMAIC (Define, Measure, Analyze, Improve, Control) framework are among the approaches widely used to support operational efficiency improvements in these manufacturing environments [1].

In regulated medical device manufacturing, any modification to a validated process must comply with strict regulatory and quality requirements. Process validation activities, including Operational Qualification (OQ) and Performance Qualification (PQ), are essential to verify that process changes do not negatively impact product quality, microbiological control, or process performance [2][3].

Critical quality parameters evaluated during process modifications may include residual chemical levels, surfactant concentration, bioburden, and physicochemical product properties. Maintaining these parameters within established acceptance criteria is necessary to ensure regulatory compliance and product performance [3][4]. Bronkhorst flow controller technology supports accurate monitoring of process flow conditions during process evaluation for this type of process improvement [5].

Methodology

A structured Lean Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) methodology was applied to evaluate and optimize water consumption within the High Volume 100 (HV100) Extraction and Hydration (E&H) process used in silicone contact lens manufacturing. This methodology enabled a systematic evaluation of the current process, identification of the major contributors to water consumption, implementation of controlled process improvements, and establishment of long-term monitoring strategies.

Define

The problem was defined as excessive deionized (DI) water consumption within the HV100 E&H process, which represented a significant portion of the overall plant utility usage and operational costs. A Project Charter, **process overview/mapping** (Figure 1) activities, and **stakeholder** alignment sessions were used to establish the project scope, objectives, process boundaries, and key stakeholders involved in the project. The project scope was limited to manufacturing operations, specifically focusing on the E&H rinse stage where continuous DI water flow is required during production. The primary objective was to reduce the water flow rate from 10 L/min to 5 L/min while maintaining product quality and process performance under regulated manufacturing requirements.

Measure

Baseline measurements and **data collection** activities were conducted to quantify water consumption and evaluate current process performance. Analysis of operational parameters confirmed that the E&H process operated with a constant DI water flow rate of 10 L/min, resulting in an estimated annual water consumption of approximately 34 million gallons. **Pareto** analysis was used to identify the major contributors to water usage across manufacturing business units. Figure 2 shows that HV100 represented the primary contributor within the manufacturing scope. Additional data stratification within HV100 was performed to evaluate process-level consumption.

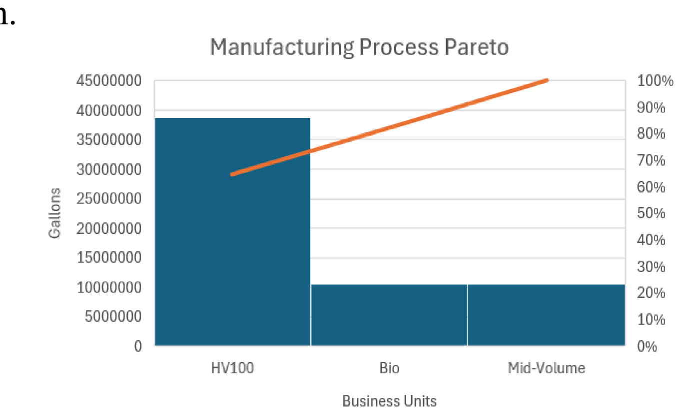

Figure 2. Pareto Analysis of Water Consumption by Manufacturing Business Unit

Analyze

As shown in Figure 3, a detailed sub-analysis **pareto** within HV100 was performed to identify the primary drivers of water consumption at the process level. Root cause analysis, **worst-case analysis**, and process evaluation activities were performed to identify the primary drivers of excessive water consumption within the E&H process. Results demonstrated that the high DI water flow required during rinse operations was the main contributor to excessive water usage. The analysis also confirmed that the existing process conditions provided an opportunity to optimize water consumption through controlled reduction of flow rate while maintaining adequate removal of residual substances and acceptable process performance. Worst-case conditions were evaluated to ensure that the proposed changes would not negatively impact microbiological, process, or product quality requirements

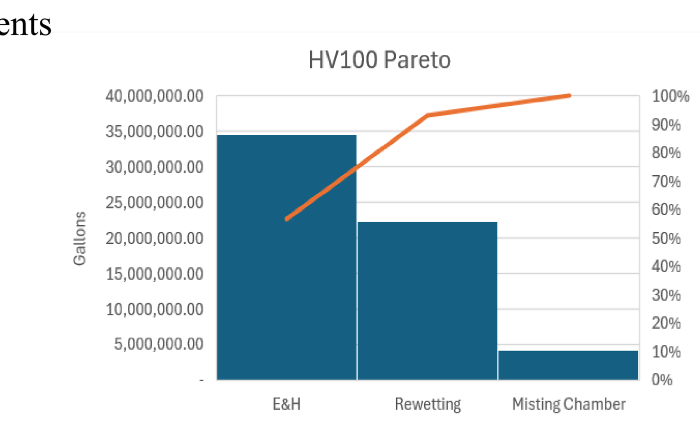

Figure 3. Pareto Analysis of Water Consumption within High Volume 100 (HV100)

Improve

Engineering Studies (ES), Operational Qualification (OQ), and Performance Qualification (PQ) activities were conducted to evaluate and validate the proposed reduction of DI water flow from 10 L/min to 5 L/min under both worst-case and normal manufacturing conditions. A structured sampling plan was implemented to evaluate critical process, microbiological, and product quality parameters. Parameters evaluated included residual alcohol levels, Tween80 concentration, bioburden, optical characteristics, visual defects, and material properties. Table 1 summarizes the critical parameters evaluated during the validation activities. Results demonstrated acceptable process performance and product quality under reduced flow conditions, supporting implementation of the proposed optimization strategy

Table 1
Engineering Study Parameters Evaluated

Parameter	Category	Sampling	Results
Tween80	Process	n=3 (solution)	Pass
Residual Alcohol	Process	n=3 (solution)	Pass
Bioburden	Microbiological	n=20 (lens)	Pass
Lens Optical Characteristics	Product Quality	n=288 (lens)	Pass
Lens Visual Defects	Product Quality	n=288 (lens)	Pass
Lens Material Characteristics	Material physicochemical	n=3 (lens)	Pass

Control

Control charts, routine monitoring activities, and **SOP/MNT revisions** will be established to ensure long-term process stability and sustainability following implementation of the reduced flow conditions. A three-month monitoring strategy will be developed to continuously evaluate water flow rate, residual alcohol levels, Tween80 concentration, bioburden, and additional product quality indicators. These activities will be implemented to verify continued compliance with operational and regulatory requirements while sustaining the reduction in water consumption achieved through the project.

Results and Discussion

The proposed improvement was integrated into the existing manufacturing system by reducing the water flow rate within the Extraction and Hydration (E&H) process from 10 L/min to 5 L/min through a Human Machine Interface (HMI) setpoint adjustment. The implementation did not require programming modifications or mechanical changes to the existing equipment, allowing the optimization to be applied using existing process control capabilities. Figures 5 and 6 illustrate the measured reduction in daily water consumption and the projected reduction in annual water consumption following implementation of the reduced flow conditions.

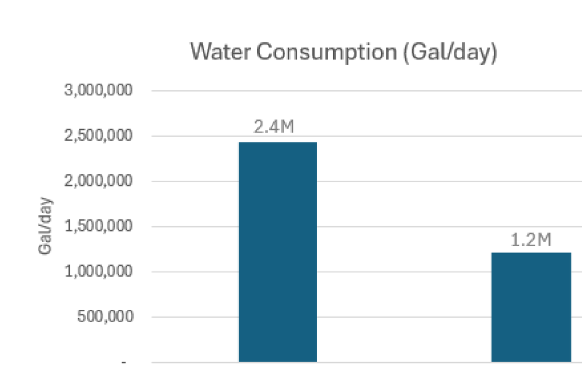

Figure 4. Daily Water Consumption Reduction

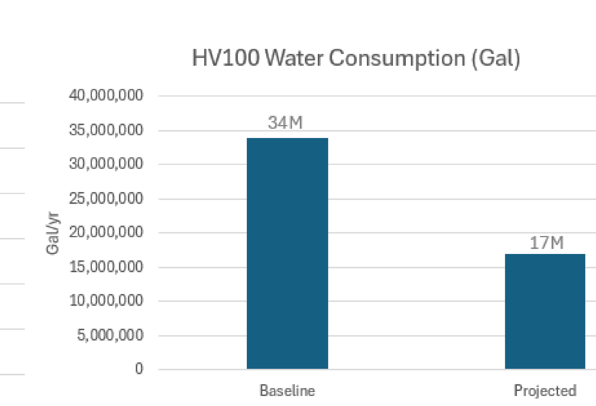

Figure 5. Annual Water Consumption Reduction Projected

Following successful completion of the Engineering Study (ES), Operational Qualification (OQ) and Performance Qualification (PQ) activities were executed using sampling plans established by the Quality and Statistical Analysis departments. The OQ was performed under worst-case conditions using the 20 alcohol reuse cycle condition within the ELMA Extraction and Hydration process, while the PQ was executed under normal manufacturing conditions using three production lots processed at the reduced flow rate.

Critical process, microbiological, and product quality parameters including Tween80 concentration, residual alcohol levels, bioburden, optical characteristics, visual defects, and material properties met predefined acceptance criteria throughout validation activities. Results confirmed that the reduced flow conditions maintained acceptable process performance and product quality with no adverse trends or abnormal process variability observed.

Following successful validation on the qualified production line, implementation across the remaining production lines was executed through approved Work Orders (WO) based on established process equivalency. Table 2 summarizes the validation activities and results.

Table 2
Summary of Validation Activities and Results

Validation Activity	Lot	Condition	Results*
Operational Qualification	1 lot (-10.00D Power)	Worst Case – 20 alcohol reuses	Pass
Performance Qualification	3 lots (Low-Med-High Power)	Normal Manufacturing	Pass

To support long-term sustainability of the implemented improvement, a three-month monitoring strategy including routine sampling activities and control chart analysis will be utilized to monitor parameters such as Green Bioburden, Bioburden, residual alcohol levels, and Tween80 concentration.

Conclusions

The lean six sigma DMAIC methodology provided a structured approach to identify and implement a water reduction strategy within the HV100 extraction and hydration process. Process evaluation and pareto analysis identified the DI water rinse stage and the 10 L/min flow rate as the main contributors to excessive water consumption. Engineering study (ES), operational qualification (OQ), and performance qualification (PQ) activities confirmed that reducing the flow rate from 10 L/min to 5 L/min did not negatively impact process robustness, microbiological control, or product quality attributes. All evaluated parameters remained within established acceptance criteria. The proposed optimization is expected to reduce annual DI water consumption by approximately 50%, decreasing usage from nearly 34 million gallons to approximately 17 million gallons annually, while maintaining process stability and regulatory compliance.

Finally, the Control phase will establish a continuous monitoring strategy, including routine sampling plans, control chart analysis, and SOP/MNT document revisions over a three-month monitoring period to ensure long-term process stability, sustainability, and continued compliance with operational and regulatory requirements.

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