DERMABOND Topical Skin Adhesive Sampling Plans Optimization Project between Ethicon San Lorenzo & Cornelia

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Abstract

This project investigates the optimization of sampling plan for DERMABOND Topical Skin Adhesive products, focusing on reducing lead times for the Critical to Quality attributes: viscosity, purity, and packaging peel strength. Currently, each raw material and finished goods lot undergoes extensive testing, which this study proposes to evaluate for potential reductions based on product homogeneity. Through the application of statistical techniques, including Mann-Whitney tests and Two-sample T-tests, the research aims to establish the feasibility of reducing testing frequency. The goal of this study is to achieve a 75% reduction in lead times by Q4 2025, which would improve product release timelines and customer satisfaction. The expected outcomes recommend a streamlined quality assurance process in Ethicon, decreasing testing time by two hours per lot and reducing overall lead time by 20.5 days. This study highlights the importance of data analysis in enhancing manufacturing sampling plans and improving the cost of quality.

Introduction

DERMABOND Topical Skin Adhesive is a designed for rapid wound closure following surgical procedures, and it comes in three product families: Prineo, Advanced, and High Viscosity Dermabond (HVD). The primary formulation is manufactured at Ethicon's facility in Cornelia, GA, where it undergoes rigorous testing for viscosity and purity before processing at San Lorenzo into Finished Goods (FG) lots. These lots are then sterilized and returned for final testing.

Figure 1: Dermabond Supply Chain Process Flow

This research focuses on optimizing the testing of Critical to Quality (CTQ) attributes—viscosity, purity, and packaging peel strength. It proposes reducing redundancy in testing by conducting a homogeneity evaluation that allows for a subset testing strategy based on raw material formulations. Furthermore, the study aims to correlate pre-sterilization and post-sterilization peel strength data to streamline quality assurance processes.

Background

In today's competitive market, organizations must continuously improve product and service quality to maintain success. Customer satisfaction is vital, and variability in product specifications must be eliminated through Process Capability Analysis, which assesses the accuracy of production processes to ensure consistent quality and reliability.

Since 1997, Ethicon has been producing 2-octyl cyanoacrylate formulations for wound closure devices, which include a monomer and various modifiers. These formulations, primarily used in DERMABOND Products, undergo viscosity and purity testing upon arrival at the Cornelia facility. The proposed approach aims to reduce testing by ensuring viscosity and purity levels are consistently maintained across finished goods lots from the same formulation.

Background (Cont.)

Additionally, packaging for DERMABOND FG lots is evaluated for peel strength at the Ethicon San Lorenzo site, with testing occurring at the beginning and end of production runs. After sterilization, samples are tested at the Cornelia facility. The new methodology suggests correlating pre-sterile and post-sterile peel strength data to streamline the quality assurance process, thereby reducing the peel strength testing.

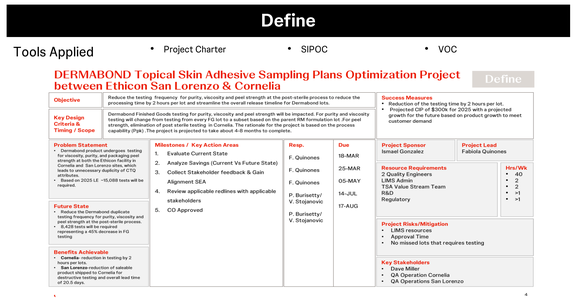
Problem

- The project's main objective is to achieve a 75% reduction in FG testing lead time by the end of Q4 2025, improving operational efficiency and enhancing customer satisfaction. The key contributions include reducing processing time by 2 hours per lot and decreasing the lead time for FG lot releases by 20.5 days.

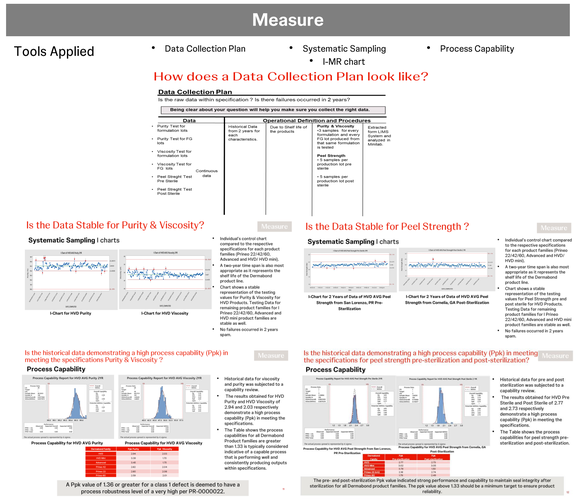
Methodology

The methodology for this project focuses on implementing the Six Sigma DMAIC framework at Ethicon Cornelia and San Lorenzo to achieve a 75% reduction in the lead time for DERMABOND products. This framework consists of five key phases:

Results and Discussion



Results and Discussion (Cont.)



Conclusions

The assessment of historical data for Dermabond products over a two-year span reveals a stable manufacturing process with high process capability concerning purity, viscosity, and peel strength. The consistency in purity and viscosity across finished goods from the same parent lot suggests that testing can be streamlined. Mann-Whitney tests support that purity and viscosity assessments for Dermabond product families be limited to one finished good lot per formulation parent lot.

Moreover, the evaluation indicates that post-sterilization peel strength for Dermabond Advanced products demonstrates superior performance compared to pre-sterilization, although it shows lower Ppk values. Two-sample T-tests support the conclusion that post-sterile samples exhibit significantly stronger seal strengths. Consequently, it is recommended that peel strength testing be conducted solely during the manufacturing process in San Lorenzo, PR. This adjustment could lead to a further reduction in testing time at Cornelia, GA, cut down the overall lead time by approximately 20.5 days, and eliminate the requirement for destructive testing on marketable products.

Future Work

This research has made significant contributions to the Dermabond end-to-end process. By implementing the proposed changes, the lab capacity in Cornelia, GA, can be increased, resulting in a reduction of testing time by 2 hours and lead time of 20.5 days for Dermabond lots and a more efficient production process overall. However, limitations of this study include potential variability in testing conditions and the reliance on historical data, which may not account for future changes in processes or materials. These findings lay the foundation for optimizing operations and enhancing product quality in the Dermabond production process.

Acknowledgements

I would like to express my sincere gratitude to Prof. Jose A. Morales, PhD, for your invaluable guidance and support throughout this journey. Additionally, I extend my thanks to Dr. Ismael Gonzalez for your insightful feedback and encouragement, which helped shape my research. I also appreciate the constructive criticism from reviewer Joann Casillas, which significantly enhanced the quality of my work. Thank you all for your support.

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