Case Study:

Design for Six Sigma in New Product Development – Conductive Pipette Tips

Background

A global liquid handling equipment manufacturer required a new phthalate-free pipette tip material to be produced in the U.S. The goal was to achieve the same strict specifications and quality criteria as their established European product while using locally available raw materials. This development was part of a **U.S. government initiative, in collaboration with the U.S. Department of Defense and the Department of Health and Human Services (HHS), aimed at strengthening local supply chain security** in critical medical and laboratory products. At the same time, the mutual goal was to ensure reliable scale-up to U.S. production with minimal delays or quality risks.

Challenge / Need

The customer needed a locally produced compound for pipette tips for IVD tips e.g. for PCR and antibody testing that:

- Matches European benchmark performance standards.
- It is **phthalate-free** and suitable for sensitive diagnostic applications.
- Can be transferred to U.S. production with minimum effort.
- Is high quality, consistent and homogenous from batch-to-batch

The project called for a systematic and analytical approach to ensure right-first-time results.

Solution

Premix applied a **Design for Six Sigma (DFSS)** methodology to accelerate development and minimize raw material loss. The DFSS process follows the steps of **Plan, Identify, Design, Optimize** and **Validate (PIDOV)**. This is a systematic approach to understand the Critical to Quality factors and how to achieve excellent performance and stability for the new product.

The product formulation was first developed and optimized at Premix's R&D center in Finland using U.S.-sourced raw materials. During the production trial phase Premix's experts **conducted on-site trials with several formulations directly at the customer's facilit**y. Based on those results, the first extended production campaign was executed, followed by a **comprehensive DoE-based optimization** to fine-tune the compound for consistent full-scale performance. Longer confirmation runs with the optimized process control factors yielded stable quality, excellent performance and more positive customer feedback. The new compound was ready to be transferred into production in the U.S. plant!

Formulation Design and Optimization

The first phase of the project took approximately **six months**, during which significant effort was dedicated to laying the groundwork for a successful formulation. Referring to this stage merely as "selecting raw materials" would understate the comprehensive scope of work carried out.

Key steps in Premix's **DFSS (Design for Six Sigma)** approach included:

1. **Raw material sourcing and qualification:** A rigorous global search was conducted to identify and secure suitable U.S.-based raw materials. This involved evaluating supply security, compliance, and performance suitability.
2. **Project planning and boundary setting:** The technical and commercial scope was jointly defined, narrowing down viable implementation paths for transitioning from the European formulation to a U.S.-localized equivalent.
3. **Comparative analysis and risk assessment:** Multiple technical alternatives were investigated and ranked based on performance simulations, feasibility, and regulatory implications.
4. **Raw material testing and benchmarking:** Candidate materials underwent targeted testing to validate compatibility and predict final product properties.
5. **Pilot compounding and evaluation:** Several pilot-scale compounds were developed and tested to simulate full-scale processing behavior and property replication.

6. **Pilot Scale Trials**
   - Produced small-scale test batches
7. **Customer Feedback**
   - Initial testing showed excellent results, confirming the material's potential.
8. **Process Optimization in Production Scale**
   - A **Central Composite Design (CCD) DoE** to model the process and optimize process parameters for production-scale line
9. **Confirmation Runs**
   - Defined the product specifications by means of statistical methods
   - Confirmed consistent quality output and process capability at the required standard
   - Set the product under **Statistical Process Control (SPC**) and define the control limits
10. **Customer Feedback**
    - Validate the performance of the material from full scale production line
11. **Production Start-up in the U.S.**
    - Launched full production with **SPC monitoring** and on-line metrics to ensure stability and Six Sigma-level quality performance.

Results / Benefits

- ☑ **High Quality, First Time Right:** The U.S.-produced material met the same strict performance criteria as the European reference product.
- ☑ **Six Sigma level Electrical Performance:** Achieved stability and consistency at Six Sigma levels despite raw material differences.
- ☑ **Cost & Resource Efficiency:** Fewer recipe iterations required, saving time and development costs. Despite being one of the most extensive and demanding product development projects Premix thanks to **effective planning, focused execution, and a well-structured approach** significant reduction of work needed was achieved and project was well within budget.
- ☑ **Customer Satisfaction:** The solution enabled smooth local production, ensuring supply security and alignment with sustainability and compliance requirements.

This case demonstrates how **Design for Six Sigma (DFSS)** can be strategically applied in complex new product development to **optimize formulation, accelerate validation**, and **secure full-scale U.S. production** that meets **the most stringent global quality standards**.

Get in touch with us

Whether you have questions about our wide range of plastic compounds and materials or need assistance, our team is here to help.

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